Appendix A

Informal Public Comments for COMAR 10.24.01 Draft Regulations posted July 26, 2022

1. Gallagher Evelius & Jones
2. LeadingAge Maryland
3. Hospice & Palliative Care Network
4. Maryland- National Capital Homecare Association
5. Health Facilities Association of Maryland Partners in Quality Care (HFAM)
6. Baker Donelson
7. Law Offices of James A. Forsyth
8. Maryland Hospital Association
9. LifeSpan Network
10. University of Maryland Medical System
11. Tidal Health
12. Holy Cross Health
13. Office of the Attorney General's Health Education and Advocacy Unit (HEAU)

GALLAGHER
GALLAGHER EVELIUS & JONES
ATTORNEYS AT LAW

September 19, 2022

VIA EMAIL

Alexa Bertinelli
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Maryland Health Care Commission
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Alexa.Bertinelli@maryland.gov

Re: MHCC Proposed Procedural Regulations, COMAR § 10.24.01 et seq., Informal Comments Submitted by Gallagher Evelius & Jones LLP

Dear Ms. Bertinelli:

We write to provide informal comments on the Maryland Health Care Commission's proposed amendments to its procedural regulations, COMAR § 10.24.01 *et seq.* (the "Proposed Regulations"), which were presented for informal review and comment on July 26, 2022.

We recognize the significant effort that went into the Proposed Regulations and appreciate the opportunity to provide comment. We urge the Commission to adopt the Proposed Regulations consistent with the modifications discussed below and with due consideration to comments others may raise.

I. General Comment Regarding Proposed Regulations Concerning Comparative Review

We note some inconsistencies in the Proposed Regulations as to the time period during which a comparative review may be triggered, and in other instances note that the Proposed Regulations may overly burden applicants with comparative reviews or delay in docketing of their applications in situations that may make such delay or additional procedure unwarranted. We propose several comments to improve predictability to applicants and to limit the potential delay or increased procedures to those situations where most appropriate.

Subsection .07A(6) provides that upon submission of a letter of intent that "might be comparable to an application which has been submitted but not yet docketed, the projects shall be given a comparative review." This subsection appears to undermine the tight time limits on when a letter of intent or application may trigger a comparative review elsewhere in the regulations. For example, Subsection .07A(4) indicates that receipt of a letter of intent

not subject to a review cycle shall trigger publication notice and a 30-day notice period for submission of letters of intent in the same service area to be included in the same review, presumably as a comparative review. Proposed Regulation .07A(6) would make the time period established in .07A(4) irrelevant, as if a potential applicant for the same service in the same service area missed the 30-day period, it could simply wait until the primary application was filed and then file its letter of intent, triggering a comparative review under .07A(6).

Moreover, the explicit limitation of .07A(4) to applications *not* subject to a review cycle indicates that applications subject to a review cycle shall not face the potential of a comparative review based on a later-filed LOI. Under proposed .07A(6), however, if an application were still pending at the time the review cycle next permitted a filing, filing of a new letter of intent could trigger a comparative review. This scenario is more than a remote possibility – under Proposed Regulation .08A(2), an application may not be docketed if there is a pending application for the same service in the same service area, leaving the potential that an application may be pending for some time before docketing.

We propose that the various triggers for a comparative review be closely reviewed and a consistent approach taken to the time period during which an applicant may expect a potential comparative review. We further propose an outside limit on the time period for a comparative review to be triggered, inserted wherever appropriate, and believe such a limit will allow parties to plan and prepare more appropriately than the unknown and potentially lengthy time under the Proposed Regulations as currently drafted. We provide the following for consideration:

> "Notwithstanding any other regulation in this Chapter, no letter of intent or application shall initiate a comparative review with an earlier filed letter of intent or application if the earlier filed letter of intent predates the later filed letter of intent by a period of more than 60 days, unless the Executive Director finds that the applicant in the earlier filed mater has unreasonably delayed in the advancement of its application through Staff's completeness review, and that good cause exists to review the projects in comparative review."

We further note that "might be comparable" as used in subsection .07A(6) replaces language in existing regulation requiring that the projects "be determined to be comparable by the Commission." We suggest the .07A(6) be revised to indicate who shall make the determination, and submit that "might" is too vague a word and too law a hurdle in light of the significant increase in procedure and resources required to complete a comparative review. We suggest the following revision for consideration, without waiving the concerns advanced above as to the open time frame permitted by the Proposed Regulation:

> "(6) If a letter of intent is submitted for a proposed health care project which ~~might be~~ the Executive Director determines is comparable to a project application which has been submitted but not yet docketed, the projects shall be given a comparative review. Comparable projects must, at a minimum, be in the same health planning region and involve the addition or expansion of a least one of the same medical services."

Finally, in light of the increase of resources, procedure, and time imposed by a comparative review, as well as the potential open-endedness of the period during which a comparative review may be triggered under .07A(6), especially as combined with .08A(2), we submit that a comparative review is not appropriate for two projects in the same health planning region, even submitted at the same time, if the most recent need projections for the health planning region in which the proposed projects are or will be located if approved would support the implementation of both projects. We provide the following for consideration, to be inserted wherever it may be appropriate:

> "Notwithstanding any other regulation in this Chapter, proposed projects shall not be considered in a comparative review if the most recently published need projections for the service(s) included in the proposed projects would support

the implementation of both projects, unless either party files comments as an interested party in the other review."

For the same reasons discussed above, we proposed the following changes to .08A(2):

"(2) In a case when need for additional service capacity is projected, the Commission shall not docket an application until it has made a final decision on each previously docketed application for a ~~similar~~ project~~.~~ seeking to expand or implement the same medical service in the same health planning region, unless the most recently published need projections the service would support the implementation of both projects, or if the applicant in the docketed review consents."

II. Comments on Specific Proposed Regulations

A. Regulation .01, Definitions

Certain defined terms in the proposed procedural regulations differ from how such terms are defined in the authorizing statute(s). We propose that the definitions in the proposed procedural regulations match the corresponding statutory definitions. In particular, we propose revising the definitions for the following terms as set forth below.

1. "Ambulatory surgical facility"

To align with the definition in Md. Code, Health-General § 19-114(b), we propose that "Ambulatory surgical facility" be defined as follows:

"(5) "Ambulatory surgical facility" means ~~a~~ any center, service, office, facility, or office of one or more health care practitioners or a group practice~~health care facility or part of a health care facility with three or more operating rooms~~ that:

(a) Has three or more operating rooms;

~~(a)~~(b)Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

(c) Seeks reimbursement from a third-party payor as an ambulatory surgical facility."

2. "Certificate of need"

To align with the definition in Md. Code, Health-General § 19-114(c), we propose that "Certificate of Need" be defined as follows:

"(12) "Certificate of Need" or "CON" means ~~an approval~~ a certification of public need issued by the Commission ~~for specified health care projects~~ under Health-General Article, Title 19, Annotated Code of Maryland."

3. "Certificate of ongoing performance"

To align with the definition in Md. Code Health-General § 19-120.1(a)(3), we propose that "Certificate of ongoing performance" be defined as follows:

"(13) "Certificate of Ongoing Performance" means an approval issued by the Commission that ~~specific~~ the cardiac surgery services, emergency PCI services,

or elective PCI services provided by an acute general hospital meet standards evidencing continued quality under Health-General Article, § 19-120.1, Annotated Code of Maryland."

4. "Health care services"

To align with the definition in Md. Code, Health-General § 19-120(a)(3)(i), we propose that "Health care services" be defined as follows:

"(24) (i) "Health care services" means clinically-related patient services.

(ii) "Health care service" includes a medical service."

5. "Limited service hospital"

To align with the definition in Md. Code, Health-General § 19-301(h), we propose that "Limited service hospital" be defined as follows:

"(34) "Limited service hospital" means a health care facility that:

(a) Is licensed as a hospital on or after January 1, 1999;

(b) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;

(c) Retains an emergency or urgent care center; and

(d) Complies with the regulations adopted by the Secretary under Health-General Article, §19-307.1, Annotated Code of Maryland."

6. "Local health department"

To align with the definition in Md. Code Health-General § 19-114(g) we propose that the term "Local health department" instead be defined as "Local health planning agency," as follows:

"(36) "Local health planning agency ~~department~~" means the health department in a jurisdiction or a body designated by that jurisdiction to perform health planning functions."

7. "Medical Service"

We recommend subcategory (ix) of medical service be separated into two subcategories, as the Proposed Regulation currently contains references to two medical services within this numbered item. We wish to avoid any potential dispute, however remote, that these services are the "same service" as that term is used in the Proposed Regulations.

"(ix) Intermediate care for alcohol and drug abuse withdrawal management and treatment; or ¶

(x) Intermediate care for persons with intellectual disabilities; or"

***8.* "*Religious Order*"**

New proposed regulation .01B(50) defines "religious order, which requires that members of the religious order to "have devoted their lives to religious service, *to the exclusion of lay life and activities*." *Id*. § .01B(50)(b) (emphasis added). We believe that this definition is too restrictive and fails to recognize that many religious orders and their members engage in activities such as teaching, the provision of health care services, and other secular activities in furtherance of their religious missions. Accordingly, we suggest Regulation .01B(50)(b) be amended as follows:

"(50) "Religious order" means an incorporated, not-for-profit organization:

(a) That is owned or is wholly operated by an entity founded and operating for the sole purpose of carrying out religious precepts; and

(b) Whose members have taken the vows required by the order and have devoted their lives to religious service~~, to the exclusion of lay life and activities~~."

9. "Residential Treatment Center"

We propose adding a definition for Residential Treatment Center, not currently defined in this chapter, consistent with the Commission's treatment of this term as related to services governed by COMAR 10.07.04, and not including residential treatment center services as that term is used by providers of certain substance-use disorder treatment services. The proposed definition is copied, verbatim, from COMAR 10.07.04.

"(##) "Residential Treatment Center" means a related institution as defined in Health-General Article, §19-301 *et seq.*, Ann. Code of Maryland, and licensed under COMAR 10.07.04, that provides campus-based intensive and extensive evaluation and treatment of children and adolescents with severe and chronic emotional disturbance or mental illness who require a self-contained therapeutic, educational, and recreational program in a residential setting whose average length of stay averages between 12 and 18 months."

B. Regulation .02, Coverage

For clarity, we recommend that Regulation .02A(4)(e) be amended to eliminate the reference to "freestanding" ambulatory surgical facilities ("ASFs"). We are aware of no

other procedural regulations referencing "freestanding" ASFs. The regulation should amended to state:

"Establishes a new home health agency, general hospice care program, or ~~freestanding~~ ambulatory surgical facility."

C. Regulation .03, Non-Coverage

1. Numbering Corrections, .03F(1), Changes in Bed Capacity

We recommend formatting changes to Regulation.03F(1) to re-letter subsections (a) through (h), as there are three subsections lettered .03F(1)(c) in the Proposed Regulation.

2. .03F(1)(b), Changes in Bed Capacity for Mergers and Consolidations

Proposed Regulation .03F(1)(b) governs non-coverage for increases or decreases in bed capacity between health care facilities. As written, however, the regulation appears to only apply to hospitals. Further, romanette (c) should be (i). We recommend that regulation .03F(1)(b) be amended as follows:

"(b) The change is proposed pursuant to a merger or consolidation between health care facilities, the ~~hospital~~ health care facilities notify~~ies~~ the Commission at least 45 days before the proposed change in bed capacity of its medical services, and the Commission finds that the change:

(~~c~~i) Is not inconsistent with the State Health Plan;

(ii) Will result in the delivery of more efficient and effective health care services; and

(iii) Is in the public interest[.]"

D. Regulation .04, Exemptions from CON Review

1. Broaden Reference for Types of Facilities Required to have Public Informational Hearings

Regulation .04D(1) should be amended to reference health care facilities other than hospitals that are required to hold public informational hearings, as required by Maryland Code, Health-General § 19-120(l)(3) and Regulation .03C(3), as follows:

"An acute general hospital, or other health care facility as determined by the Commission in accordance with Maryland Code, Health-General § 19-120(l)(3) and Section .03C(3) of this chapter, shall hold a public informational hearing in the county where it is located within 30 days after it has filed with the Commission notice of its intent to:" [close, partially close, or convert to a limited service hospital or freestanding medical facility.]"

E. Regulation .07, Preapplication Procedures

We propose the following clarification to proposed regulation .07A(4), concerning comparative reviews:

"(4) Notice of the receipt of a letter of intent for a project not subject to a published review schedule shall be placed in the Maryland Register, and a 30-day period initiated for the submission of any other letters of intent ~~for~~ including the same medical service in the same planning region to be included in ~~the same~~ a comparative review."

F. Regulation .08, Procedure for Review of CON Applications

1. Notice to the Public, 08D(2)

Maryland Code, Health-General Article § 19-120 requires the Commission publish notice in *the Maryland Register* of its receipt of an application for certificate of need for a change in the bed capacity of a health care facility or for a health care project that would create or abolish a new health care service. The changes proposed to the Commission's public notice procedures in proposed regulation .08D(2) spring from filing of the letter of intent or from docketing. To the extent the proposed changes are intended to replace the notice provided at the time of receipt of an application rather than supplement that with additional notice, a statutory amendment would be required. We further support the Commission providing publication notice for the first time earlier than docketing, which would not provide sufficient time for potential interested parties to review all materials, determine to seek interested party status, and prepare comments.

G. Regulation .11, Evidentiary Hearings

1. Typographical and numbering corrections

We recommend the following changes in Regulation .11 to correct typographical and numbering errors.

Regulation .11B(1)(xi):

(x) Issue orders as are necessary to secure procedural simplicity and

administrative fairness and to eliminate unjustifiable expense and delay; and

(xi) Conduct the hearing in a manner suited to ascertain the facts and

safeguard the rights of the parties to the hearing.~~; and~~

Regulation .11F(3):

.11F(3) The reviewer may set reasonable time limits on the cross-examination

of witnesses.

H. Regulation .12

1. Typographical corrections

The word "and" appears to be missing from Regulation .12A(1)(c) as follows:

"(c) The time required to complete the approved construction, renovation, or both following initiation of construction, renovation, or both~~.~~; and"

Additionally, the word "regulation" is appears to be misspelled in Regulation .12E(3):

"(3) The holder has failed to obligate or complete an approved project as required by §A of this regulation~~r~~."

2. .12E(5), Reference to Progress Reports

Regulation .12E sets forth the grounds upon which the Commission may withdrawal a CON or other Commission approval, including the failure the holder's failure "to timely provide the annual progress report required under §A of this regulation[.]" Proposed Regulation .12B governs progress reports, which are semi-annual not annual. Accordingly, Regulation .12E(5) should be amended as follows:

"(5) The holder failed to timely provide the semi-annual progress report required under §~~A~~B of this regulation[.]"

I. Regulation .19, Reconsideration Procedures

We suggest revisions to .19A, Request for Reconsideration, to confirm that a party may seek reconsideration not only from a "Commission approval," but more broadly from a "Commission decision." The proposed regulation, as currently worded, would have the illogical effect of granting parties who seek relief other than a CON or CON exemption the right to reconsideration if the request is approved, but not if the request is denied. We further suggest moving the language "For good cause shown." In its current location, it appears to impose the requirement of good cause on the making of the request – that is, that a party must show good cause in order to make a request for reconsideration.

We believe that good cause should more appropriately be a condition of the relief requested, which appears consistent with the intent of this regulation based on the substance of .19B and .19D.

"A. Request for Reconsideration. ~~For good cause shown, a~~An aggrieved party may request that the Commission conduct a hearing to reconsider a Commission final decision to grant, to grant with conditions, or to deny a Certificate of Need application, a request for an exemption from CON review, or other Commission ~~approval~~ decision issued under this chapter. This request shall be in writing and filed with the Center for Health Care Facilities Planning and Development within 15 days of the date upon which the Commission renders its decision. The aggrieved party bears the burden of showing good cause for the relief requested."

* * * * *

Thank you for your consideration of these comments. Please contact us if you have any questions.

Sincerely yours,

Thomas C. Dame

James C. Buck

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September 19, 2022

VIA EMAIL: alexa.bertinelli@maryland.gov
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SUBJECT: Informal Public Comment COMAR 10.24.01 Certificate of Need Health Care Facilities

Dear Ms. Bertinelli:

LeadingAge Maryland is a community of not-for-profit aging services organizations serving residents and clients through continuing care retirement communities, affordable senior housing, assisted living, nursing homes and home and community-based services. We represent more than 140 not-for-profit organizations, including the majority of CCRCs in Maryland, as well as skilled nursing centers, assisted living communities, affordable senior housing, continuing care at home programs, hospice, and home and community-based services providers. Our mission is to expand the world of possibilities for aging in Maryland. We partner with consumers, caregivers, researchers, faith communities and others who care about aging in Maryland.

LeadingAge Maryland thanks you and the Maryland Health Care Commission (MHCC) for the opportunity to comment on the proposed regulations under COMAR 10.24.01, Certificate of Need (CON) Health Care Facilities.

I. General Observations.

We appreciate the work of the Maryland Health Care Commission (MHCC) CON Modernization Task Force and Governor Larry Hogan's 2015 Regulatory Reform Commission which was the impetus for these proposed regulations. LeadingAge Maryland also recognizes the

significant changes in the MHCC's enabling statute since COMAR 10.24.01 was last modified in 2015. Many of the areas below could benefit from further discussion and examination. Our general comments are as follows:

A. In general, the CON process is cumbersome. The current CON process is cumbersome and arduous on applicants. In our review of the proposed regulations, MHCC is provided more power and oversight than the previous regulations. This makes Maryland an even more challenge state in which to operate healthcare settings. For instance, the length of time it takes to work through CON application process can be 2-3 years. This costs providers significant resources in lawyer fees, which is particularly burdensome for our members who are not-for-profit organizations.

B. Allow flexibility in counties where there is only one hospice CON given. In smaller counties, like Charles County and Calvert County, there is only one CON given. This gives no option of choice to families who need to seek hospice services for a loved one. We would suggest allowing support from a hospice in a neighboring county, if so requested by the underserved jurisdiction.

C. Expiration on CONs that are issued but not utilized. For example, some hospices in the state have received a CON but they are not utilizing it; it's akin to squatting. If there is a CON issued, demonstrating that there is need, an organization should have a given amount of time to address that need. For example, one thought is if a hospice provider is not utilizing an issued CON within a certain timeframe, that CON could be awarded to another hospice provider.

D. Support change of ownership provisions. Currently the Office of Health Care Quality (OHCQ) approves change of ownership. We are unclear under the proposed regulations who has final authority. What happens if OHCQ and MHCC disagree? Further, the proposed regulations require identification beyond the owner to include information about affiliations of the owner and source of funds for making the purchase. Our members applaud and are supportive of steps to promote transparency and encourage that this process be carefully discussed so as to not unnecessarily delay transfers of ownership or potentially disrupt the lives of individuals receiving care in a nursing home.

E. Concerns over requirement to hold public informational hearings. This appears to apply to not only new home health business, but also to providers who wish to de-license bed capacity. For example, a CCRC that wishes to reduce its SNF bed capacity would first need to hold a public hearing. There are many reasons a skilled nursing unit may need to be downsized or closed and decisions often involve complex business and financial considerations. This requirement is overly burdensome on the

provider especially given the fact that stakeholders may not fully understand or appreciate the drivers behind the decision.

II. Specific Concerns.

A. .01(B)(2) Definitions. We have confusion around what exactly is meant by "adversely affected". Further clarity would be appreciated.

B. .03(D)(4) Non-Coverage by Certificate of Need or Other Commission Approval. We strongly recommend that MHCC eliminates the requirement that limits a facility from requesting de-licensure of beds more than one time in a 12-month period.

C. .03(K)(4) Non-Coverage by Certificate of Need or Other Commission Approval. We recommend change to 10 percent, not 20 percent- based on residents going home on home health and not as many going to comprehensive care. This would allow for more external admissions.

D. .08(C)(3) Procedure for Review of Application. LeadingAge Maryland supports placing time limits on MHCC in its request for additional information.

E. .09(E)(3) Commission Decision and Action on CON Applications. A 6-month stay of an application review is too long. MHCC should have adequate number of reviewers prepared at any time to not unnecessarily extend the review period for applicants.

F. .10(A)(2) Miscellaneous Rules and Procedures – What is meant by a "a reasonable period of time"? Further clarity would be appreciated.

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We understand that a workgroup to review these proposed regulations has not been formed yet, but the Commission may consider convening a workgroup in the future depending on the volume of comments received. Given the significant challenges with the CON process, LeadingAge Maryland urges that a workgroup is formed focused on high interest areas.

LeadingAge Maryland greatly appreciates the opportunity to provide these comments. Please contact me if you have any questions.

Sincerely,

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Hospice & Palliative Care Network
OF MARYLAND

Via Electronic Mail
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September 19, 2022

Mr. Ben Steffen, Executive Director
Maryland Health Care Commission
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Dear Mr. Steffen,

On behalf of the Hospice & Palliative Care Network of Maryland (HPCNM), we appreciate this opportunity to share our members' comments on the proposed changes to Title 10 Maryland Department of Health Subtitle 24 Maryland Health Care Commission Chapter 01 Certificate of Need Health Care Facilities COMAR 10.24.01 as noted below. Our comments are based on the page numbers of the redlined copy.

Pages 1 and 7 – .02 Definitions of Adversely Affected and Interested Party:

HPCNM Comment: HPCNM is seeking clarification but expresses its initial concern regarding the changes being made to the definitions of adversely affected and interested party. From our read, it appears that the changes have limited the circumstances for when an interested party would be considered "adversely affected." Currently, there are four circumstances for when an interested party is considered "adversely affected." The draft deletes as a standalone the provision that an interested party can be adversely affected on the basis that the interested party could reasonably provide the proposed services. Instead, the draft now qualifies it by demonstrating that the approval would either "materially affect the quality of care" or "result in a substantial depletion of essential personnel." No other reasons would then be permitted. Given that this definition and the definition of interested party refer to this decision being made solely by the reviewer, we are concerned regarding its limiting affect and the subjectivity of the reviewer without clear standards of how either qualifier would be evaluated.

Page 19 - .03 Acquisition of a Comprehensive Care Facility, Home Health Agency, or Hospice:

HPCNM Comment: HPCNM applauds the MHCC for including these additional requirements that stems fraud and abuse with the additional transparency requirements for new applicants who wish to enter the market.

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Page 26 - .03 Acquisition of a Comprehensive Care Facility, Home Health Agency, or Hospice:

HPCNM Comment: HPCNM is unclear on the rationale for expanding the CON exemption for a health maintenance organization (HMO) under Section G. Currently, an HMO is exempt from the requirements provided that the service being sought is to be used "exclusively by the subscribers." This draft changes it to state that the CON exemption is permitted if at least 90% of the patients who will receive health care services are enrolled in the HMO. Why this expansion? How will the MHCC monitor the 90%?

Page 46 – .08 Procedure for Review of CON Application/Other Provisions:

HPCNM Comment: In various provisions of the draft, the term "reasonable" is used, most often when it is referring to establishing time limits or providing extensions for further submission of information. It seems that the term "reasonable time limit" is vague and needs to be more specific. The last time several HPCNM members filed for a CON, the process took more than two years which limited hospice care to those communities who were identified as having a need for services. In addition, this delay was very costly for CON applicants.

Page 50 – (3)(a)(b) Relating to Need:
(a) State Health Plan. An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

(b) Need. The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served and established that a need for the proposed project meets those needs.

HPCNM Comment: HPCNM is concerned that removing "the unmet needs of the population to be served" and replacing it with simply "the applicant has demonstrated need for the proposed project" overly weakens the review process. HPCNM believes that it is crucial for this to remain.

Page 51 - (f) Project Impact on Existing Providers and the Health Care Delivery System:

HPCNM Comment: The edits remove any review of potential negative impact on current providers unless they file in writing to be an interested party with objections.

The State of Maryland recognizes 18 out of the 24 counties/jurisdictions as rural. Maryland's rural counties include Allegany, Calvert, Caroline, Carroll, Cecil, Charles, Dorchester, Frederick, Garrett, Harford, Kent, Queen Anne's, Somerset, St. Mary's, Talbot, Washington, Wicomico, and Worcester. HPCNM would like to see, among the proposed changes, a different strategy that addresses the 'need' and the 'project impact' to incorporate the differences that affect rural areas.

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Page 55 – .09 Commission Decision and Action on CON Application:

HPCNM Comment: Section E (3) states that "[a] *review of a CON application may be stayed for a period not to exceed six months if the review, or if a reviewer is not appointed by the Executive Director determines that there is a good cause for stay."* This provision again seems vague and does not fall within the spirit of streamlining the CON process to expedite the needs of a community in need of hospice services, and the avoidance of unnecessary time and expense to applicants. Discussion should be on shortening the six months to 90 days, which coincides with the 90 days for acting on an application after docketing with no evidentiary hearing.

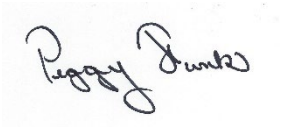
Page 60 –.10 Miscellaneous Rules and Procedures:

HPCNM Comment – Section K is new language that allows the MHCC to move items to a consent agenda, which includes a change in an approved project. While we have reviewed Regulation .17 regarding permissible and impermissible changes, we would like to better understand the circumstances that may fall into this provision.

Page 72 – .12 Holder Responsibilities and Withdrawal of a Certificate of Need:

HPCNM Comment – Section E lists areas for the withdrawal of a CON approval for various reasons, including that the approved applicant failed to demonstrate sufficient progress in implementing the project. This revision does not include any timeframes. Given past experiences with the implementation of certain projects, we do believe a discussion is warranted on this change.

Sincerely,



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cc: Alexa Bertinelli, Assistant Attorney General

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September 19, 2022

Delivered via email to Alexa Bertinelli -MHCC- alexa.bertinelli@maryland.gov

Alexa Bertinelli
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Dear Ms. Bertinelli:

Thank you for providing us with the opportunity to respond to the proposed draft amendments to COMAR 10.24.01 regarding the procedural regulations applicable to the Certificate of Need (CON) review process for health care facility planning and development. MNCHA understands that the overall goal of the MHCC CON Modernization Task Force has been to realign 10.24.01 with the statutory and regulatory changes that have taken place since its last update over a decade ago. We appreciate the thoughtful work of the Task Force, and we also recognize that this work has taken place in addition to the daily responsibilities of your team.

Overall, MNCHA supports these draft amendments as they relate to the Home Health Agencies. Our impression is that there are a variety of protections for current CON holders, yet clearly-defined requirements and proof of need thresholds for future applicants. We are pleased that the Task Force has considered a boarder scope of acquisition activity as a reflection of current marketplace trends and included additional protective provisions based on related risks. Additionally, there appears to be an expansion of Certificate of Ongoing Performance provisions that provides added scrutiny and protections against fraud, waste, and abuse.

There are a few areas within the draft that we suggest you clarify and/or revisit. We request that MHCC reconsider the anticipated impact that a CON exclusion for HMOs can have on current CON holders. Given current trends in the marketplace, it is reasonable to expect that HMOs may increasingly pursue acquisitions of Home Health Agencies as a continuum of healthcare service provision that is closely related to the shift to home-based primary care services. MNCHA opposes that exempt status of HMOs as written, and we request that the Task Force give more thought to the serious potential for disruptive impact that HMOs providing home health services can have on the ecosystem of Home Health Agencies. Local small business owners and operators are among these agencies, and they are critical parts of this ecosystem, particularly in the rural areas of our state.

Also, MNCHA would like to request clarification for Home Health Agencies who currently hold a specialty CON and the process by which they would be able to expand their current CON. There are no provisions within these draft regulations that account for CONs previously awarded as specialty (i.e., pediatric private duty agencies).

MNCHA's additional responsive comments are detailed below:

10.24.01.01 Definitions

- There are not currently definitions for "merger" or "consolidation," yet these terms are referenced in latter sections of 10.24.01. Can definitions for these terms please be added to this section?
- B.(3). Clarification: what, if any, are the substantive changes to the rights of an aggrieved party?
- B.(9). Clarification: is the definition of a capital expenditure expanded such that a project that would previously not have required a CON review would now require one?

10.24.01.02 Coverage

- A.(4).(f). This provision references the elimination of an existing medical service. Can you please confirm that this provision does not apply to a Home Health Agency that, for example, will no longer offer Occupational Therapy services?

10.24.01.03 Non-Coverage

- H. This provision references that a Home Health Agency must notify MHCC if opening a branch office, though a new branch office does not require a CON review. Does this only apply if the branch office is within the agency's currently defined service area? We would like to clarify the distinction between a new branch office versus a new service area. Would it make sense to add these as relevant definitions?

10.24.01.22 Effective Date

- B.(1). It appears that the intent of this provision is to allow for a mechanism to review projects that were previously approved. MNCHA opposes this as written and requests that language be added to specify the scope and parameters of such a review. And would this type of determination review occur only if requested by an aggrieved party? The mechanism to carry out this determination is unclear. The total resources of the Commission should be considered, particularly given its expanded responsibilities and respective timeframes that are included in the draft amendments.

MNCHA is available if you would like to have further discussion on any of these topics, or should you determine a future need to convene a workgroup. If you have any questions, please feel free to reach out to me at chouck@mncha.org, or 240-383-0420.

Sincerely,

Caitlin S. Houck

Caitlin Houck, RN, MS
Executive Director

Cc: Danna Kauffman, Esq.

HFAM
Health Facilities Association of Maryland
Partners in Quality Care

SENT VIA EMAIL AND FEDEX

September 16, 2022

Mr. Ben Steffen, Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Draft Certificate of Need Regulations

Dear Mr. Steffen:

Thank you for all you and your team do to ensure continued access to quality care for Marylanders in need across all healthcare settings – especially skilled nursing and rehabilitation centers.

We appreciate your continued effort to work collaboratively on regulations that are data-driven and focus simultaneously on quality, access, and ensuring organizations that serve as the public safety net have a stable and predictable regulatory environment.

Finally, thank you for the opportunity to comment on the draft certificate of need ("CON") regulations developed by the Maryland Health Care Commission ("MHCC"). We offer comments and suggestions on behalf of the Health Facilities Association of Maryland ("HFAM"), representing nursing homes operating the largest number of comprehensive care facility ("CCF") beds in the State.

Our comments follow in relation to the order of the regulations. We note in the body several provisions that merit particular focus.

Definitions: Section .01

.01B (7): In defining "bed capacity" or "physical bed capacity," a discussion of shell space and surge capacity is warranted. Health care facilities should have the capability to anticipate future needs for space in a consumer-focused, market-driven, efficient, and cost-effective way.

.01B(22)(b): It is unclear why the existing definition of health care facility is amended to remove the exclusionary reference to continuing care retirement communities in light of the language of Health-General Article, Section 19-114(d)(2)(ii).

.01B(30)(a) and (b)(i): In defining "Initiation of Construction" the three references to "all" should be revised to make clear that the intention is to require the applicable permits necessary to do the work according to the appropriate construction steps to initiate construction or do the preconstruction site work, since some permits may not be needed until later points in the construction process. "All" is too broad in this context.

.01B(33)(b)(ii): Licensed bed capacity should ensure the availability of shell space or surge capacity. Health care facilities should have the flexibility to plan for and implement measures for future space needs. This is especially important as baby boomers age, and skilled nursing and rehabilitation centers continue to play a key role in providing accessible care to Marylanders fighting multiple chronic conditions.

.01B (39): It is extremely important that a merged asset system must also include a "group of entities with overlapping ownership or control." A system can function as such, not only as "an entity." We would note that in healthcare economies of scale sand shared operations provide create advantages in providing quality care.

Coverage: Section .02

02A (3): The reasons for the removal of the text from the reference to changes in bed capacity are unclear. As noted above, shell space and surge capacity are important aspects of facility planning. Waiver beds are a well-established and essential part of capacity planning. Thus, for example, the exclusion for waiver beds under the 10 beds/10% rule for nonhospital health care facilities should not be changed.

Noncoverage: Section .03

This noncoverage section merits close attention and discussion. It is an often-used, vital part of the MHCC's process.

03A (2): First, given the 30-day time frame, the regulations should include a requirement for the MHCC to issue a confirmation of the date a timely and complete notice of acquisition is received. Second, if the applicable 30-day period passes, the MHCC should issue a confirmation to the Office of Heath Care Quality since those seeking noncoverage determinations should not be in position where they are on their own to assert in the licensing process that the noncoverage determination happened by operation of the regulation, but the licensing agency needs confirmation from the CON agency.

03A (3): We are very concerned about the introduction of a new concept of a noncoverage determination process with "conditions." If the acquisition determination qualifies for noncoverage, the confirmation should issue from the MHCC. We are concerned about this new concept without definition, basis, rights to appeal and the resulting delay from the imposition of "conditions." This should be discussed fully.

.03B(1)(a)(i): To be consistent with Medicare process, disclosures at 5% or above should be the standard.

.03B(1)(b): We know this is a part of the current process, but we propose that the purchase price not be part of the determination request. The MHCC does not have authority to regulate purchase prices, and this should not be part of the regulatory process.

.03B(1)(c): The reference to Medicaid commitments should include the language "if any" since some long-standing facilities do not have such a commitment.

.03C: We have a concern with the provision that a health care facility other than a hospital may be required to hold a public informational hearing on closure. Some closures are voluntary, some are required by financial or other external events, and sometimes as part of the regulatory process. There are licensing and certification notice requirements already in effect. An effective process must be in place to ensure the timely, effective, and safe discharge of residents, while under the care of staff. Timing is of the essence. Coordination with residents, families and staff in such situations if important, though we question use of a public informational hearing as the best tool for this to occur.

.03D (4): We suggest the Temporary Delicensure process permit health care facilities to have the flexibility to request authorization for different groups of beds to be temporarily delicensed in stages without having to wait for the end of a 12-month period to make a new request for each group. The process should be more flexible and enable the facility to make such a request such as would be appropriate when a facility is undertaking renovations of different sized units in sequential fashion

.03D (8): We strongly urge that the requirement for the MHCC to give notice of the abandonment of temporarily delicensed beds under the current regulation should not be deleted. The current, available notice is important, not burdensome, and should be preserved.

<u>Preapplication Procedures: Section .07</u>

.07A (2): A further change in the draft CON regulation should be considered to permit minor changes among the owners of the entity submitting a letter of intent to occur.

.07B: The rationale for removal of the current language referring to who should be the applicant is not stated and is unclear.

.07B: If an applicant requests a preapplication conference, one should be held, in lieu of the proposed "may" language. Or one should be required unless waived by the applicant.

Procedures for Review: Section .08

.08C (3): This should refer to 10 business days. Ten calendar days is unreasonably short.

.08D (1): It is important that the current but deleted requirement that the schedule of CON reviews include a statement about the status of need forecasts is important and should be restored.

.08D (2): The current but deleted requirement for the staff to request Maryland Register publication within 10 business days should be restored.

.08E (2) and former (4): The current but deleted language in two places identifying changes to an application that are not modifications is important and should be restored. Such changes do occur, and it is disruptive to a smooth process for this change to be made. Also, minor changes among ownership of an applicant during a CON review should be permitted under a further amendment.

.08F (3): There is no limit to the number of Interested Parties or Participating Entities. Filings can be massive, yet, under the current regulation only one 25-page response is permitted. There should be additional language permitting the applicant to file, in the alternative, and without permission an additional 10 pages per set of comments where there are two or more comments.

.08G(3)(e): The new term of art "Terms" is included in the draft regulations without definition or explanation. The reference to "Terms" should be removed unless the basis and meaning for a "Term" of a prior CON separate from a Condition is established.

Commission Decision and Action: Section .09

.09A(1)(a) and (b): The two references to the "full" Commission should be removed as confusing. There are other provisions dealing with a quorum.

.09B (2): The current but deleted language referring to the timing of exceptions should be restored.

.09B (3): As noted concerning responses to comments, here too there is no limit to the number of Interested Parties or Participating Entities. Filings can be massive, yet, under the current regulation only one 15-page response is permitted. There should be additional language permitting the applicant to file, in the alternative, and without permission and additional 10 pages per set of responses to exceptions where there are two or more exception filings.

.09C: The current but deleted language referring to the role of participating entities not being interested parties and not having a right to appeal is essential and should be restored.

Miscellaneous Rules: Section .10

.10D (2): A Staff Motion for summary decision is a major event. Ten days to respond is far too short. At least 21 days should be provided.

.10G (1): There various references here and in the draft regulation to a whether a submission is "consistent" versus "not inconsistent" without clarity whether the distinction is intentional. For example, here, under .10G (1), "not inconsistent" with the State Health Plan is more appropriate.

.10K: The new concept of a "Consent Agenda" should be explained as to meaning, purpose and necessity, particularly given the breadth of Section .10K(1)(c).

Evidentiary hearings: Section .11

.11: The current but deleted reference to seeking oral argument in the question whether to hold oral argument on whether to hold an evidentiary hearing should be restored.

(The language of the current, but deleted reference to H "Notice of CON Approval" should be restored. The deletion appears in Section .11 of the draft regulations.)

.11B(1)(a)(i): The word "full" in relation to a hearing is unclear.

.11B(1)(b)(iv): It is highly problematic for the Reviewer to act as a party to the hearing and to have the authority to call witnesses. The Reviewer should act as the impartial authority. This is a major concern.

.11B(2)(g): The current but deleted language in the regulations permitting to request an opportunity to show why administrative notice should not be taken or matters are inapplicable should be restored.

.11B (4): Costs of transcription should be shared equally among any party making use of the transcript.

.11C (1): The current but deleted reference to the Reviewer shall holding a prehearing conference should be restored, unless waived by the parties. Thus, all of the current but deleted language in the regulation referring to the issues addressed in a prehearing conference should be restored as well.

Holder Responsibilities: Section .12

There is a new, major change referring to Holder responsibilities beyond a CON application, referring to "Other Commission Approvals." This is an area of deep concern since it will make the regulatory process more complex, slower and costly. The scope of this change needs to be discussed fully in relation to its scope and applicability as it would appear to impose the equivalent of CON level performance requirements on projects that do not require a CON, for the first time. This is particularly the case in relation to new Section .12A (3), requiring adherence to the project implementation schedule submitted. Projects and their timing can be affected and cannot cease precipitously such when supply chains are disrupted, public health emergencies affect workforce, a permitting process takes longer than as projected, and other factors interview. Even under current performance requirements, not all changes require approval of the Commission while notice is required. Substantial discussion is warranted concerning project schedule changes that can be accommodated through discussions with Staff.

.12(1)(c) and (d): We believe strongly that greater flexibility than the current 18-month period for renovations and non-renovations should be included in a further amendment. A process for proposing the most appropriate timing for a project should be included.

.12E and F (deleted): The effect of removal of these current regulations on performance requirement extensions and failures to meet performance requirements is unclear. Projects commence and encounter factors that need to be addressed in timely way, taking into account a myriad of contractual, financing, clinical and related equivalents. The CON regulations should envision a clear, effective way to provide notice of such factors, the ability to discuss them with Staff and to bring them to the Commission where necessary. The regulations need to include a process for securing extensions of time frames as needed without the prospect of an entirely new CON application. This is particularly important if the Commission is intending to use this regulatory change to impose a monitoring process for projects that are not subject to a CON application process.

12F (3): In lieu of using a "beyond the holder's control" standard, the regulations should use a "good cause" standard. The MHCC should not self-limit its authority to work with a "holder" to learn about and review why a project is not progressing rather than adopting an overly limiting standard particularly if the MHCC is going to adopt a regulation that requires an entirely new CON after an earlier one is withdrawn.

Special Procedures: Section 14

.14A (2): Given the 30-day process for Executive Director review, the regulations should require the agency do provide confirmation of receipt of the determination request.

Project Changes: Section .17

.17B (2): The MHCCs inflation regulation is not always the most effective. The draft regulations do refer to the use of other guidance approved by the Commission and posted on its website. The MHCC should consider permitting applicants to propose an inflationary index that is, after the CON is issued, more reflective of the project in progress.

First Use: Section .18

Here too, the scope of the draft regulations relating to approvals other than a CON merits substantial discussion. Currently First Use Approval is a concept used in relation to the CON process. There can be a major effect on the timing and implementation of other forms of projects if First Use concepts are to be applied beyond the CON process.

Again, thank you for the opportunity to comment. As you can see, in addition to making specific suggestions, we identify areas where important discussion is warranted. We believe a meeting is advisable before the Commission next considers these draft regulations. We request to be included in any meeting or task force on these draft regulations.

Be well,

Joe DeMattos, MA
President and CEO

CC: The Honorable Dennis R. Schrader, Secretary, Maryland Department of Health
Wesley Huntemann, Congregate Care Lead, Maryland Department of Health
Howard Sollins, Baker Donelson
HFAM Board of Directors

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September 19, 2022

Ben Steffen, Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: **Draft Certificate of Need Regulations**

Dear Mr. Steffen:

Thank you for the opportunity to comment on the draft certificate of need ("CON") regulations developed by the Maryland Health Care Commission ("MHCC"). We are aware of the comments submitted by our client, Health Facilities Association ("HFAM"), and support them without reiterating them to avoid duplication. There are aspects of the draft regulation on which HFAM did not comment, such as where they are not relevant to long term care, but on which we wish to comment based on our long-time experience with the CON process.

Definitions: Section .01

.01B(2): The Cross- reference to Section B(19) as reference to interested party status appears to be a typo due to renumbering within the regulations.

.01B(31)(d): The scope of jurisdictions within the definition is unclear in relation to a replacement acute general hospital CON review. First, what is the definition of a regional health system? Second, does a single hospital with a service area that extends into contiguous jurisdictions constitute a regional health system, even if the contiguous jurisdictions are not within the hospital's primary or secondary service area? Third, if a CON application is considered to propose a replacement acute general hospital by or on behalf of a regional health system, does a jurisdiction qualify under this definition even if it is not contiguous to the replacement hospital's jurisdiction? It is unclear why a jurisdiction could be an Interested Party in a CON review because it is contiguous to a service area of another health care facility operated by the regional health system but not within the service area of the replacement acute care hospital.

.01B(31)(e): Why was the reference to issue areas over which the Commission has jurisdiction removed from the language about adversely affected? We would be concerned about persons being an interested party based on allegations of adverse effect in areas beyond the jurisdiction of the Commission.

.01B(38)(a)(ix): There should be discussion about the language of Health-General Article Section 19-120 and implications of new language in the definition of Medical Service referring to Intermediate care in the regulation, including why it refers to withdrawal management without any reference to medically managed withdrawal, or what kinds of facilities serving persons with intellectual disabilities are covered. Also, is the intention that simply by the MHCC creating an inventory for service capacity that these types of Intermediate Care are included in the definition of Medical Services? Where for example existing health care facilities otherwise serve individuals with need for withdrawal management or with intellectual disabilities, they should not be considered to be offering a new or separate Medical Service. Such services can be well within the clinical purview of existing health care facility services.

.01B(40): The word "must" should be replace with "can" to recognize how multiphased plans of construction can be implemented.

.01B(43)(a)(iii): The reference in the definition of Participating Entity that is a third-party payer to a union providing a health plan to union members on behalf of the employer is unclear. Does this refer to employers who file CON applications involving locations or relocations? It should be clear that unions who are not third-party payers akin to an insurance company for the applicant in a CON review are not within this definition.

.01B(43)(a)(iv): Why are pharmacy benefit managers included within this definition of a third-party payer seeking Participating Entity status?

.01B(43(c): As a global comment, here and in other places in the proposed regulation there is a reference to "county" instead of "jurisdiction." Jurisdiction is a defined term under Section .01B(32).

.01B(48)(b)(ii): What is the purpose of the reference to physicians who are not employees of the hospital?

.01B(51)(c): The reference to an evidentiary hearing should include the phrase "if any."
.01B after (51): Why is the definition of "threshold for capital expenditures" eliminated instead of being updated? Is it simply replaced by the Hospital Capital Threshold definition?

Noncoverage: Section .03

.03J(2): As a matter of clarity, on what basis can the MHCC determine that review by the Health Services Cost Review Commission is or is not required?

Exemptions: Section .04

.04D(3)(d)(iii): This should be clarified to refer to health care needs of the residents of the hospital service area to refer to the primary service area and to the health care needs for acute general hospital services.

.04D(3)(f): There needs to be a process for the hospital obtaining more than 10 business days to meet this requirement. Not all closures will be alike.

Ambulatory Surgery Centers: Section .05

.05A(5): We are concerned about the introduction of a new concept of a noncoverage determination process with "conditions." If the ASC determination qualifies for noncoverage the confirmation should issue from the MHCC. We are concerned about this new concept without definition, basis, rights to appeal and the resulting delay from the imposition of "conditions." This should be discussed fully.

.05A(6): An additional amendment from the current language referring to "any change" in information provided should be considered. Reference to substantial changes or material changes, or specificity to the types of changes is warranted.

.05A: The deleted language after new (8) referring to office locations or relocated ASCs should be restored.

Access to information and facilities: Section .06

Is the removal of the "extent permitted by law" intended to be a material change?

Project Changes: Section .17

As a general comment, there needs to be a significant discussion of the types of Commission "approvals" other than CON applications that are subject to the Project Change process. This is a major change to the CON process that will add cost and increase workload among facilities and the Commission staff alike

First Use: Section .18

Here too, the scope of the draft regulations relating to approvals other than a CON merits substantial discussion. Currently First Use Approval is a concept used in relation to the CON process. There can be a major effect on the timing and implementation of other forms of projects if First Use concepts are to be applied beyond the CON process.

Emergency CON: Section .20

.20B: We question why a hard copy of a request for a CON in an emergency needs to be provided in "hard copy" unless it is clear that the hard copy is solely an after the fact confirmatory document.

Thank you for the opportunity to comment. As you can see, in addition to making specific suggestions we identify areas where important discussion is warranted. We do believe a meeting about them is advisable before the Commission next considers these draft regulations.

Sincerely,

Howard L. Sollins

John J. Eller /TR

John J. Eller, Jr.

HLS/lam

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September 19, 2022

Alexa Bertinelli, Esq.
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

By email to alexa.bertinelli@maryland.gov

Re: Comments on Proposed Amendments to COMAR 10.24.01

Dear Assistant Attorney General Bertinelli;

As directed, I attach my personal Comments on Staff's Proposed Amendments to COMAR 10.24.01. Please note that these Comments represent my own personal views and are not binding on any client in any pending or future matters before the MHCC.

Thank you and the MHCC for soliciting my views and the opportunity to submit them.

Very truly yours,
James A. Forsyth
JAMES A. FORSYTH, ESQ.

JAF/met

cc: Wynee Hawk, Chief CON, MHCC at wynee.hawk1@maryland.gov

COMMENTS ON MHCC'S PROPOSED REVISIONS TO COMAR 10.24.01 ET SEQ.

- COMAR 10.24.01.01 Definitions.

    - Page 1, Redline Version: B(2)(a)(i) defining adversely affected status:

        - *Change:* Add "and substantially" after the word "materially" so the revised sentence reads: "Would materially **and substantially** affect the quality of care…"

        - *Reason:* The proposed change would streamline the CON process by making it clear that a proposed new project's impact on an existing facility must be more than incidental or minor in order to qualify an existing facility as "adversely affected" and entitled to potential status as an "interested party" in a CON Review of a proposed project.

    - Page 1, Redline Version: B(2)(b) defining adversely affected / interested party status:

        - *Change:* Add "substantial" after the word "potentially" so the revised sentence reads: "Can demonstrate to the reviewer that a health care facility operated by the person could suffer a potentially **substantial** detrimental impact from the approval of a project before the Commission, in an issue area over which the Commission has jurisdiction…"

        - *Reason:* The proposed change would streamline the CON process by making it clear that a proposed new project's impact on an existing facility must be more than incidental or minor in order to qualify an existing facility as "adversely affected" and entitled to potential status as an "interested party" in a CON Review of a proposed project.

- COMAR 10.24.01.03 Non-Coverage by Certificate of Need or Other Commission Approval.

    - Page 18, Redline Version: A(1)(d) concerning information required to be submitted in connection with the acquisition of an existing health care facility:

        - *Change:* The requirement for provision of any other information requested by Commission Staff should be eliminated.

        - *Reason:* This provision is entirely open-ended and overly broad. The parties should have advance notice of what is specifically required to be submitted.

- Page 31, Redline Version: K. Continuation of Specific Exception from Certificate of Need for Continuing Care Retirement Communities:

  - *Change:* The provisions of subsection K(7) regarding direct admissions should be revised to require that CCRC Nursing Home Administrators shall submit the specified information on direct admissions quarterly to the MHCC which shall publish the information on its Public Use Data files.

  - *Reason:* This change should be made in the interest of public disclosure and to aid in ensuring that CCRC direct admissions comply with the applicable regulatory requirements.

- COMAR 10.24.01.09 Commission Decision and Action on CON Applications.

  - Page 55, Redline Version: Reg. E(3) concerning stays of CON reviews:

    - *Change:* Section E(3) should be revised to limit a stay to a maximum of 90 days instead of up to six months.

    - *Reason:* A six month stay is too long since it can increase costs and results in delays to development of needed projects. In addition, the resulting delay prevents docketing of similar proposed projects designed to meet the need for identified services.

- COMAR 10.24.01.10 Miscellaneous Rules and Procedures.

  - Page 58, Redline Version: Reg. A(1) concerning the Computation of Time:

    - *Change:* should be changed to provide that the 10 day time limit shall be based on working days and not calendar days.

    - *Reason:* Applicants should have a reasonably sufficient time to respond to deadlines, as recognized by the Commission in its regulations. The preparation of CON Applications and responsive documents are usually undertaken by several individuals working as teams. Team members are not regularly available on weekends and holidays. Accordingly, time periods should be calculated on the basis of working days as they have been in the past.

- <u>COMAR 10.24.01.12 Holder Responsibilities and Withdrawal of a Certificate of Need or Other Commission Approval.</u>

    - Page 72, Redline Version: Reg. E concerning availability of extensions of performance requirements:

        - *Change:* The provisions of current Reg. 12 E should be retained and remain in effect so as to provide for the extension of any applicable Performance Requirements.

        - *Reason:* Unless CON Holders retain the ability to obtain extensions of applicable performance requirements for circumstances beyond their control, the orderly development of needed health care projects will be jeopardized. Likewise, without the ability to obtain stays of performance requirements, opponents of a project, including NIMBY- motivated opponents of projects are incentivized to 'run out the clock' on needed projects by filing successive appeals of required local government approvals, including land use approvals. Neither of these outcomes is in the public interest and they also frustrate the goals and purposes of the health planning and CON processes.

[END]

Maryland
Hospital Association

September 19, 2022

Alexa Bertinelli
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 20215

Dear Ms. Bertinelli:

On behalf of the Maryland Hospital Association's (MHA) 60 member hospitals and health systems, we are pleased to participate in the informal comment period for changes to COMAR 10.24.01, Establishment of and Other Actions Related to Health Care Facilities and Services. We appreciate the MHCC's diligence updating these important regulations and commitment to streamlining the Certificate of Need (CON) process. Overall the changes provide additional clarity, maintain fidelity to the legislative intent of modernizing CON, and will improve transparency in the process. However, there are a few instances that warrant further discussion by the Commission.

Commission staff are vital to the CON process and maintain a level of regulatory authority that is important to the health care system, but staff judgement should not replace Commission action when needed. Throughout the draft document it appears staff authority is expanded. For example, changes made to the determination of coverage process for every service and industry regulated under CON allow for commission staff to issue a determination that a CON is not required *with conditions.* While there are times where certain issues need to be resolved before staff can advise a CON is not needed, conditions should be pertain to aligning the project with CON regulations and not further additional policy aims. **The Commission should discuss the balance between staff authority and necessary Commission action**.

The draft regulations further streamline the process by adding a timeframe of 120 days after docketing for a project to be deemed approved (page 48 of the final draft). While the exemption from this deadline for new hospitals, replacement facilities, cardiac surgery and organ transplantation seems warranted, as these large project may require additional time to review, the regulations do not speak to any time requirements for these CON reviews. **The Commission should consider whether a blanket exemption from CON review timelines is warranted or if these complicated reviews should still be subject to some time constraints or review deadlines, with the possibility of extension.**

Lastly, we welcome clarification of which stakeholders are eligible for interested party status, and what entities are eligible for participating entity designation. Both interested parties and participating entities serve important roles in a CON review. All relevant stakeholders deserve to

be heard to give the Commission a full and rich understanding of the potential impacts of the project on a community. Given the unique legal position of entities granted interested party status, this status should be limited to those stakeholders most proximally impacted by the proposed project.

We appreciate your time and attention and look forward to continuing this dialogue and improving the regulations.

Sincerely,

Erin M. Dorrien

Erin M. Dorrien
Vice President, Policy

Keeping You Connected…Expanding Your Potential…
In Senior Care and Services

September 19, 2022

Sent via email
Ben Steffen,
Executive Director
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, Maryland 21206

Dear Mr. Steffen:

On behalf of LifeSpan Network, we appreciate the Maryland Health Care Commission (MHCC) releasing draft regulations for comment on COMAR 10.24.01: *Certificate of Need and Other Actions Related to Health Care Facilities and Services.* Overall, LifeSpan supports the changes and appreciates the MHCC's attention to several items that our members raised during previous discussions. LifeSpan also supports the formation of a workgroup to discuss issues either raised below or raised by other stakeholders.

Below are items that we believe still need to be addressed from the redlined version of the document.

Regarding the definitions on pages 1 and 7, the draft appears to narrow the circumstances for when a person is determined to be "adversely affected" and therefore an "interested party." The changes limit the ability for a person who is authorized to provide the same services in the same planning region or contiguous planning region to be an "interested party" unless that person can demonstrate approval would materially affect the quality of care or a substantial depletion of essential personnel. It then appears that this determination will be made solely by the reviewer. We believe that this unjustly narrows the definition and that "in the reviewer's sole discretion" is fraught with subjectivity.

On pages 16 and 26, changes are made regarding the ability for a health maintenance organization to be able to be exempt from a certificate of need. Current regulations state that the service or facility must be used "exclusively by the subscribers." The changes reduce this requirement to at least 90% of subscribers. Why is this change needed and has there been any requests by HMOs to build a facility or offer health care services that would typically require a CON?

On page 22 of the draft, there is a technical change to the provision prohibiting a health care facility from requesting authorization by the MHCC to temporarily delicense bed capacity or the entire health care facility more than one time in a 12-month period. The technical change is

without issue; however, it does highlight this issue. If a health care facility can demonstrate a need to temporarily delicense bed capacity, why should it not be able to do it more than one time in a 12-month period? There have been situations, particularly during renovations, that this ability would be beneficial. Likewise, LifeSpan believes that, if the impetus of these revisions is to streamline the process, then a discussion should commence regarding expanding the circumstances when a CON is not required to include when an owner/operator is permanently reducing bed capacity. In this situation, the operator/operating must spend both time and money, which does not seem to advance the public interest.

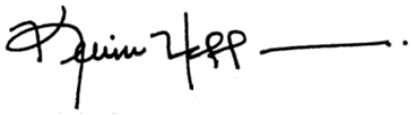
Overall, in streamlining the CON process, there must be special attention given to timeframes. Too often, the CON process has gone without resolution for one or two years, causing applicants time and money. Below are some specific comments regarding timeframes, but LifeSpan believes a dialogue is needed to determine more fully what are "acceptable timeframes." This also extends to a dialogue on how the process should address those that may have been awarded a CON but have not begun providing the service in a timely manner.

Some examples from the document include on pages 46-47, in Section (C) of Regulation .08, the regulation/revisions alternate between stating "10 business days" to "10-day deadline." Given this short timeframe, for clarity, LifeSpan recommends that this regulation and elsewhere in the regulation always reference "10 business days" to avoid confusion. Likewise, on page 58, in Section (A) of Regulation .10, there is new language added that states that "unless otherwise noted, all time periods shall be computed in calendar days." This time limit may be sufficient when the period is of the lengthier variety; however, timeframes under 10 days should be "business days."

In addition, the regulations often use the term "reasonable" when referring to the MHCC setting "reasonable time limits," such as when supplying requested information (page 46) or submitting a document or performing any act permitted or prescribed by the regulations (page 58). Given the time and cost involved in the CON process, applicants should have greater certainty in the schedule. Too often, the CON process taken more than one or two years. While unexpected situations may occur, LifeSpan believes again that there should be dialogue on the appropriate timeframes other than "reasonable" and how to then build flexibility into those timeframes. As part of that dialogue, LifeSpan does not believe, without further dialogue, it is reasonable to allow a CON application to be stayed for a period not to exceed six months as permitted by the revisions to Section (D) of Regulation .09.

Again, we appreciate the ability to submit these initial comments and we look forward to further discussions.

Sincerely,



Kevin Heffner
LifeSpan Network, CEO

cc: Alexa Bertinelli (alexa.bertinelli@maryland.gov)
Danna Kauffman, Schwartz, Metz, Wise & Kauffman

TidalHealth™

Executive Office

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September 19, 2022

Alexa Bertinelli
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Proposed MHCC Procedural Regulations, COMAR § 10.24.01 et seq.
Informal Comments Submitted by TidalHealth

Dear Ms. Bertinelli,

I write on behalf of TidalHealth, Inc. ("TidalHealth") to submit informal comments to the Maryland Health Care Commission's proposed amendments to its procedural regulations, COMAR § 10.24.01 *et seq.* (the "existing regulations"), presented for informal review and comment on July 26, 2022 (the "Proposed Regulations").

In preparing its comments, TidalHealth reviewed the written comments submitted by the University of Maryland Medical System ("UMMS"), and TidalHealth supports a number of the UMMS comments, as identified herein.

TidalHealth values the opportunity to comment on the Proposed Regulations. TidalHealth considers the Commission's efforts in amending the existing regulations an important opportunity to ensure that the Commission's procedural rules effectively advance the health planning goals of the State, while reducing burden on health care providers. As a result, TidalHealth supports the steps already taken by the Commission in the Proposed Regulations to expedite review of projects, reduce the time and expense associated with Certificate of Need and other Commission reviews, and to modernize the CON process overall. TidalHealth further supports a number of additional recommendations raised by UMMS, as discussed in more detail on the following pages.

1. The Commission should prioritize the efficient and expeditious review of provider applications through rules that also maintain the rights of applicants to participate in the review.

TidalHealth appreciates the Commission's adoption of procedural rules that result in deemed approvals for certain types of projects. TidalHealth notes that such streamlined processes advance the interests of both the Commission and of Applicants to reduce the time, cost, and burden associated with new project reviews. TidalHealth also notes, however, that the Commission has eliminated certain important rights of parties to participate in the review that TidalHealth urges to Commission to retain, such as the right to request and participate in oral argument. To appropriately balance the important goal of reducing the time associated with Commission reviews with the rights of applicants to be involved in the review, TidalHealth supports and joins in the following informal comments submitted by UMMS:

a. Automatic or deemed approvals should occur when certain conditions are satisfied or when the Commission or Commission Staff have not acted on an application within a particular time frame (UMMS Informal Comment 1.B).

b. The Commission should revise the Procedural Regulations to ensure just and fair processes for interested party participation, provide applicants with a meaningful opportunity to file exceptions to a recommended decision, allow for stays of applications in appropriate circumstances, and render decisions in a reasonable period of time (UMMS Informal Comment II.H).

c. The Commission's procedural regulations governing the review of Certificates of Conformance and Certificates of Ongoing Performance should be revised to set reasonable limits on the completeness process and additional information requests by Commission Staff, provide for more expeditious action on an application, remove references to conditions, and allow applicants sufficient time to file exceptions on a recommended decision (UMMS Informal Comment II.L).

d. Applicants should have the right to request oral argument in all instances where currently permitted by the existing regulations (UMMS Informal Comment II.P).

e. An applicant should have the right to seek consideration by the full Commission if the Commission Staff determines to deny an emergency CON (UMMS Informal Comments II.Q).

2. The Commission should adopt revised Procedural Regulations that will reduce the burdens on providers throughout the review and approval process.

Historically, applicants have at times experienced lengthy review processes that involve multiple rounds of voluminous requests for information, many of which force applicants to incur costs and dedicate scarce resources to preparing responses. TidalHealth supports the following informal comments submitted by UMMS to reduce the burdens on health care providers during the review and approval process:

a. Filings and notices should be published to the Commission's website (UMMS Informal Comment I.C).

b. Progress reports, obligation of capital, and post-approval project changes requirements should not be extended to projects that are not subject to CON review (UMMS Informal Comment I.F).

c. Proposed Regulation .04 should be amended to provide clarity around the exemptions process, including which entities qualify as the affected public, public hearing requirements, and deemed approvals, among other clarifications (UMMS Informal Comment II.D).

d. Proposed Regulation .07 should be revised to permit identification of a prospective applicant in the letter of intent and to make the letter of intent timeline more flexible (UMMS Informal Comment II.F).

e. The Commission should reduce the regulatory burden associated with completeness review and modify the general review criterions as set forth in detail in the UMMS Comments (UMMS Informal Comment II.G).

3. The Commission should adopt recommended changes to its Proposed Regulations that avoid conflict between the procedural rules and the applicable State Health Plan chapters and that provide further clarification to defined terms.

TidalHealth notes that the Commission's Procedural Regulations are rarely reviewed and updated, whereas the State Health Plan chapters undergo more frequent reviews. To avoid conflicts in the standards, criterion, and definitions that apply to projects, TidalHealth supports the following informal comments of UMMS:

a. The procedural rules should cross-reference or incorporate by reference the applicable State Health plan chapter for substantially similar requirements rather than restating them in the procedural rules to avoid conflicting definitions and standards (UMMS Informal Comment I.D.).

b. The modifications to each defined term presented in the UMMS Informal Comment II.A should be incorporated into the Commission's Proposed Regulations.

Thank you for your consideration of these comments. Please contact me if you have any questions.

Sincerely,

Christopher C. Hall
Vice President/ Chief Business Officer\

cc: Ruby Potter, Program Manager

HOLY CROSS HEALTH

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September 19, 2022

VIA EMAIL

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Re: Proposed MHCC Procedural Regulations, COMAR § 10.24.01 et seq.
Informal Comments Submitted by Holy Cross Health

Dear Ms. Bertinelli:

I write on behalf of Holy Cross Health ("Holy Cross") to submit informal comments to the Maryland Health Care Commission's proposed amendments to its procedural regulations, COMAR § 10.24.01 *et seq*. (the "existing regulations"), presented for informal review and comment on July 26, 2022 (the "Proposed Regulations").

In preparing its comments, Holy Cross reviewed the written comments submitted by the University of Maryland Medical System ("UMMS"), and Holy Cross supports a number of the UMMS comments, as identified in Section 4 below.

Holy Cross appreciates the opportunity to comment on the Proposed Regulations and share the following feedback. The amendment of the procedural regulations presents an important occasion for the Commission to further align its procedures with important health planning goals. Among the most important goals is supporting institutions that provide quality and cost-effective health care and that innovate to improve outcomes, promote equity, strengthen the economic health of communities, and advance the overall health of relevant populations. Thus, the regulations should not overburden health systems with time-consuming and expensive processes. However, this interest must be balanced with measures to ensure that parties are fully informed of the matters under consideration and can communicate and advocate effectively before the Commission. The regulations should further support the important Commission goal to work in concert with the Health Services Cost Review Commission

and providers to preserve Maryland's "all-payor" system by ensuring that projects that receive approval are cost effective, efficient, and do not substantially adversely impact existing providers that are serving the needs of their populations well.

1. **The Commission should communicate promptly and effectively with the public and parties interested in Commission approval processes.**

The Commission's timely communication with the public and parties interested in certificate of need ("CON") proceedings and other Commission approval processes is vitally important. At times, especially at the end of an approval process, CON reviews and other approvals can move quickly, leaving little time for parties who wish to be heard to have a meaningful opportunity to participate. Thus, Holy Cross urges the Commission to adopt UMMS's suggestion that all public notices and filings be posted on the Commission website within a specified time period. Holy Cross requests that the regulations specify that notices and filings should be posted on the Commission's website as soon as possible, and no later than two business days after the subject notice or filing is available.

The quality of the Commission's decision-making is improved by comment and participation from parties with a strong interest in the matters before the Commission. In addition to providing full and timely information to those who may be affected by the Commission's decisions, it is also important to allow applicants and interested parties to be heard on their positions to the Commission staff, reviewers, and the commissioners. Accordingly, Holy Cross urges the Commission to retain the rights of applicants and interested parties to provide oral argument on matters of dispute. The Proposed Regulations remove the right to oral argument in several contexts, including on a request for evidentiary hearing (Regulation .11A) and on reconsideration of final decisions (Regulation .19). These rights should be restored.

2. **The Commission should provide notice and engage in an analysis of adverse impacts before approving the relocation of a facility.**

By statute and under current Commission procedural rules, the Commission may approve the relocation of a facility within a merged asset system without a CON review if the relocation site is within the primary service area of the facility, or of the merged asset system, and the relocation project will not exceed the capital expenditure threshold for CON review. A relocation within the same jurisdiction and primary service area may be approved with a determination of coverage under Regulation 10.24.01.03E. With regard to a relocation outside of the same jurisdiction or primary service area of the facility, the party seeking approval must seek an exemption under Regulation 10.24.01.04A(2). Since the General Assembly increased capital expenditure thresholds, and the thresholds no longer restrict any facility other than a hospital, existing law

provides merged asset systems with significant opportunity to relocate facilities without CON review.

The relocation of a facility without a CON review, such as for a special hospital or a freestanding medical facility, can adversely affect the residents of the relevant service area and other providers without providing those parties with the ability to participate in the approval process. Among other adverse effects, the relocation can limit access for patients and burden emergency departments and other outpatient services for providers near the facility's original location. In light of these circumstances, at a minimum, it is imperative that the Commission's procedural rules require timely notice to other parties and an opportunity to be heard.

Holy Cross urges the Commission to require a party seeking to relocate a facility – whether by determination of coverage or through an exemption – to provide notice to all providers of the same service in the same jurisdiction as well as all general hospitals in the same jurisdiction. Specifically, Holy Cross proposes the following modifications to Proposed Regulations 10.24.01.03E and .04A(2):

10.24.01.03E:

> (2) At least 45 days before the proposed relocation, notice is <u>provided to general hospitals and providers of the same service in the jurisdiction of the facility and</u> filed with the Commission, which will publish notice of the proposed relocation on the Commission website and in the Maryland Register and a newspaper of general circulation in the affected area; and

10.24.01.04A(3):

> (3) The Commission shall solicit comment from the affected public, in evaluating whether the action or project proposed for exemption from CON review is in the public interest. <u>With respect to the relocation of a facility under subsection A(2), or the merger or consolidation of facilities under subsections A(3) or A(4), the party seeking the exemption shall provide a copy of the request, within five days after filing, to all general hospitals and providers of the same service in the jurisdiction of the facility as well as in the jurisdiction of the relocated facilities, beds or services.</u>

3. Interested parties should be informed of, and permitted to participate in, the review of post-approval project change requests, and the Commission should have greater authority to enforce compliance with the conditions and commitments an applicant made in prior CONs when issuing a new CON.

The public and interested parties should be fully informed of any requests for post-approval project changes for a previously approved CON, and they should be provided a meaningful opportunity to be heard. Sometimes, project change requests propose substantial modifications, and they can change the nature of the original approval. For example, following the Commission's CON approval for the relocation of Adventist HealthCare's Washington Adventist Hospital from Takoma Park to White Oak, AHC requested several post-approval project changes that gutted its commitment to maintain a health care campus in Takoma Park while still neglecting to provide all services committed to provide on either the White Oak or Shady Grove campuses. The commitment to maintain certain services for the residents of Takoma Park was an important consideration in the approval of the CON. Interested parties in the initial review should be informed of any post-approval project change requests and they should have the opportunity to comment, and if appropriate, present argument to the Commission. Accordingly, Holy Cross supports the informal comments submitted by UMMS regarding Proposed Regulation 10.24.01.17A.

In addition, Holy Cross urges the Commission to give the Chair discretion to allow an interested party, upon request, to submit written comments and present oral argument to the full Commission. Thus, Holy Cross proposes the following addition to Proposed Regulation 10.24.01.17D:

> (3) Upon motion by an interested party in the initial review, attaching proposed written comments, the Commission, in the discretion of the Chair, may grant such party leave to submit the written comments; further, upon request, the Chair may grant an interested party in the initial review the opportunity to present oral argument to the full Commission.

For similar reasons, Holy Cross urges the Commission to adopt changes to Regulation .08G(3)(e), Compliance with all Terms and Conditions of Previous Certificates of Need, in order to increase the Commission's authority to hold applicants to the conditions and commitments of prior CONs. Once an approved CON facility or service is built and licensed, there is little opportunity for the Commission to review or enforce a condition or commitment made by the applicant in that review, even a condition or commitment that spans into the future. Holy Cross urges the Commission to establish authority for it to seek and enforce a plan of correction prior to issuing any new CON to an applicant that has failed to follow through on its promises, and believes such a process is crucial to holding applicants responsible to commitments they may make to their service area population

> "(e) Compliance with all Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous CON granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met. Where an applicant has failed to meet a condition or commitment of a prior CON, the Commission may impose, as a condition of approval, conditions designed to correct the applicant's noncompliance. Such conditions may include, but are not limited to, a requirement that the applicant provide a plan of correction to meet any unmet conditions or commitments, and that the applicant must agree to report on its progress in any application or other request for Commission decision or approval until the Commission finds that the applicant is no longer in noncompliance. Any party that participated as an interested party in the review that gave rise to the unmet condition or commitment shall be given notice of, and an opportunity to comment on, a party's written notice and explanation as to why conditions or commitments were not met and any proposed plan of correction.

4. Holy Cross supports and joins in many of the informal comments submitted by UMMS.

In addition to the discussion above, Holy Cross also supports and joins in the following informal comments submitted by UMMS:

a. Automatic or deemed approvals should occur when certain conditions are satisfied (UMMS Informal Comment I.B.).

b. The procedural rules should refer to the applicable State Health plan chapter for substantially similar requirements rather than restating them in the procedural rules (UMMS Informal Comment I.D.).

c. The definition of "bed capacity" should be clarified to exclude observation beds and emergency department treatment spaces (UMMS Informal Comment II.A.3).

d. The word "freestanding" should be removed from Proposed Regulation 10.24.01.02A(4)(c) (UMMS Informal Comment II.B.2).

e. The Commission should impose a mechanism to ensure that HMO projects that are excepted from CON coverage meet the statutory requirements for the exception (UMMS Informal Comment II.C.3).

f. The term "partial closure" should be defined to exclude temporary closures and staffing related issues, and the requirements for a public informational hearing should be modified as suggested by UMMS (UMMS Informal Comment II.D.4).

g. The procedural rules for a determination of coverage to establish or modify an ambulatory surgery center should not duplicate the provisions of the State Health Plan (UMMS Informal Comment II.E.).

h. The pre-application procedures should be relaxed to make filing letters of intent easier for applicants (UMMS Informal Comment II.F.).

i. The proposed procedural regulations for the CON review process should be modified consistent with the UMMS Informal Comments (UMMS Informal Comment II.G.1-5.)

j. The proposed criteria for review of CON applications, criteria .08G(3)(a), State Health Plan Standards, .08G(3)(d), Project Financial Feasibility and Facility or Program Viability, and .08G(f), Project Impact, should be modified consistent with the UMMS Informal Comments (UMMS Informal Comment II.G.6, 8, and 10). Holy Cross in particular stresses the importance of maintaining the existing language in Regulation .08G(3)(d), as proposed by UMMS, to maintain the consideration of financial and nonfinancial resources and ensuring community support. Holy Cross stresses the importance of community engagement in the provision of healthcare services in a region and believes the changes UMMS recommends appropriately ensure that the

Commission will continue to consider voices the community may raise regarding a proposed project.

k. Holy Cross supports the Proposed Regulations amending the criteria for review of CON applications as to .08G(3)(b), Need, and 08G(3)(c), Alternatives to the Project. (UMMS Informal Comment II.G.7.).

l. The Proposed Procedural Regulations on the procedures for certificates of conformance should be modified consistent with the UMMS Informal Comments (UMMS Informal Comment II.L.).

m. The Commission should allow flexibility in selecting the inflation allowance index in COMAR 10.24.01.17B(2) (UMMS Informal Comment II.N.2).

* * *

Thank you for your consideration of these comments. Please contact me if you have any questions.

Sincerely,

Kristin H. Feliciano

Kristin H. Feliciano
Chief Strategy Officer
Holy Cross Health

cc: Norvell V. Coots, M.D., President and Chief Executive Officer, Holy Cross Health
Becky Vaughan, Director of Strategy, Holy Cross Health

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September 19, 2022

Via email: eileen.fleck@maryland.gov

Eileen Fleck
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RE: Informal Comments on COMAR 10.24.01 Draft CON Replacement Regulations

Dear Ms. Fleck:

Thank you for providing the Office of the Attorney General's Health Education and Advocacy Unit (HEAU) the opportunity to *informally* comment on the Draft CON Replacement regulations. Because many of the State Health Plan regulations have yet to be updated, including the State Health Plan for Facilities and Services: Acute Care Hospital Services (January 26, 2009), and because the Draft CON Replacement regulations require applicants to comply with relevant State Health Plan standards, we believe the Draft CON Replacement regulations must, at a minimum, include the fundamental tenets of the State Health Plan in the criteria for review of CON applications, determinations of coverage, and project changes.

For example, proposed 10.24.01.08G(3)(a), Criteria for Review of Application, State Health Plan, should be amended to say, "State Health Plan. An Application for Certificate of Need shall be evaluated according to all relevant State Health Plan standards, *to ensure efficient delivery of and improved financial and geographic access to appropriate quality health care services for all Marylanders at an affordable cost*." The same tenets must also guide the Commission when issuing determinations of coverage and considering project changes.

The HEAU similarly urges the Commission to include Health Equity, Character and Competence, and Legal Compliance Criteria in 10.24.01.08G(3) and determinations of coverage and project changes criteria. We propose adding this language:

Health Equity Criteria. The Commission shall consider how a proposed activity would meet the needs of the medically underserved, rural residents, low-income individuals, racial and ethnic minorities, people with disabilities, LGBTQ+ individuals, and the elderly.

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Health Advocacy Unit Toll Free (877) 261-8807 ♦ Home Builders Division Toll Free (877) 259-4525 ♦ Telephone for Deaf (410) 576-6372
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Character and Competence. The Commission shall assess the character and competence of an applicant based upon experience and past performance in operating a health care service or facility including records of violations, if any, and whether a substantially consistent high level of care was maintained. Applicants without experience in health care services or facilities should be evaluated based on compliance with laws and practices pertinent to their professional experience.

Compliance with Applicable State and Federal Laws. The Commission shall ensure that that the project will be operated and maintained in accordance with the standards prescribed by law.

The HEAU understands the Commission's goal to provide opportunities to enter the Maryland market for innovators, to minimize the regulatory requirements for existing providers to expand existing capacity or offer new services, and to reduce the burden of complying with CON regulatory requirements, but each of those goals must yield to ensuring that the delivery of health care will be affordable, accessible, safe, equitable and of high quality. The HEAU's suggested additions attempt to discourage under-resourced or irresponsible actors in certain types of care, from taking advantage of relaxed standards, and risking patient harm.

As the MHCC is aware, recently the HEAU received an influx of billing complaints related to an ASC, including complaints about collection-related litigation filed against consumers, and was also made aware that the ASC's owner's license was suspended by the Maryland Board of Physicians. That owner applied to the MHCC to expand his ASC and in 2018, staff recommended expansion despite several board orders against the owner, including a 2006 DC Board of Medicine reprimand for answering untruthfully on his license renewal application (failing to report that he lost his privileges at Washington Hospital Center), a 2009 MD Board of Physicians reprimand for answering untruthfully on his license renewal application (failing to report the DC Board of Medicine action), and a 2014 MD Board of Physicians reprimand for unprofessional conduct related to patient care. The physician was later suspended in 2021 by the MD Board of Physicians for unprofessional conduct in the practice of medicine, grossly overutilizing healthcare services, and failing to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient facility, office, hospital, or any other location in this State, based on his care of six patients.

This is the type of information that the Commission must be aware of when considering an application; it is information that should bar expansion. The HEAU's suggestions that the Commission review character and competence, and compliance with applicable state and federal laws, are a direct response to this factual scenario. Similarly, as private equity takes over nursing homes and other facilities, it is essential that the Commission study the ownership structure and compliance with applicable state and federal laws when considering applications, to ensure that health care provided by private equity backed facilities meets the State Health Plan tenets that care be affordable, accessible, safe, equitable and of high quality. Recent reporting concerning private equity backed facilities suggests that private equity firms increase costs of care while decreasing the care provided, often to harmful levels. See, e.g., https://www.newyorker.com/news/dispatch/when-private-equity-takes-over-a-nursing-home; https://khn.org/news/article/private-equity-ownership-of-nursing-homes-triggers-federal-probe/.

The Commission should require comprehensive disclosures of any adverse investigations or administrative and judicial actions relating to all individuals with ownership interests as well as the entities involved in the financing and operation of the facilities; and the vetting of these individuals and their known d/b/a entities through federal databases and State agencies including but not limited to OHCQ, MFCU, MIA, the State Board of Long-Term Care Administrators, the Long Term Care Ombudsman, and CPD, including the HEAU, and follow up as appropriate with investigations before taking any Commission action in favor of the individuals.

The HEAU would welcome an opportunity to discuss these and other issues further with you and Commission staff and wish to express our appreciation for the effort and time you have devoted to this substantial undertaking so far.

Thank you for your consideration.

Sincerely,

Kimberly S. Cammarata
Assistant Attorney General
Director, Health Education and Advocacy Unit

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CORPORATE OFFICE

September 19, 2022

VIA EMAIL

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Re: Proposed Draft MHCC Procedural Regulations, COMAR § 10.24.01 et seq.
Informal Comments Submitted on behalf of the University of Maryland Medical System

Dear Ms. Bertinelli:

I write on behalf of the University of Maryland Medical System ("UMMS") to provide informal comments to the Maryland Health Care Commission's proposed amendments to its procedural regulations, COMAR § 10.24.01 *et seq.* (the "existing regulations"), which were presented for informal review and comment on July 26, 2022 (the "Proposed Regulations").

UMMS generally supports the initiative to revise the existing regulations, and urges the Commission to propose and adopt the Proposed Regulations with the modifications discussed below.

I. General Comments

UMMS provides the following general comments regarding the Proposed Regulations.

A. Procedure to limit certain requests for information and to provide a means of producing information under seal

UMMS proposes to add a process that would permit a party or other person from whom information is sought by Commission Staff or a Reviewer to seek certain protections in limited situations where good cause is shown. The proposal contemplates that the information sought may be limited, or that it may be produced under seal – an option not currently available before the Commission. UMMS has in the past received burdensome requests for additional information that UMMS believes was not material to demonstrating compliance with the applicable review criteria or standards. UMMS has also received requests where the information was not already within UMMS control and UMMS would incur a significant cost to obtain it, or where the production of such information otherwise caused UMMS significant expense and/or delay.

In other reviews, UMMS has requested to file confidential and proprietary information under seal in cases where the Commission Staff requested information that UMMS deemed to be highly sensitive, competitive, and/or confidential, and that was not required by or material to any review standard or criteria.

Information submitted in CON reviews is typically posted on the Commission website, and Commission Staff has in the past refused requests to maintain information on a confidential basis or to, at least, maintain the information in hardcopy only without posting to the Commission's website. UMMS believes public access to matters before this Commission is generally in the public interest. However, some circumstances warrant exceptions, and parties should be afforded the same rights that litigants in Maryland courts are afforded to file certain highly sensitive, competitive, and/or confidential information under seal where good cause is shown.

Subsections 1 and 3 of the new regulation that UMMS proposes are substantially modeled on Maryland Rule of Civil Procedure 2-403 (Protective Orders). UMMS suggests the inclusion of this Rule in Section .10, Miscellaneous Rules and Procedures.

"X. Motion for Protective Order; Production of Information under Seal.

1. In any review governed by these Regulations and on motion of a person from whom information is sought, or a person named or depicted in an item sought, and for good cause shown, the Executive Director, or the Reviewer in a contested or comparative review, may enter any order that justice requires to protect a party or

person from annoyance, embarrassment, oppression, undue burden or expense, or unwarranted delay, including one or more of the following:

(a) that the request for the information is withdrawn,

(b) that the information may be had only on specified terms and conditions,

(c) that certain matters not be inquired into or that the scope of the information sought be limited to certain matters,

(d) that information be provided to and maintained by the Commission Reviewer and/or any interested party or party in a comparative review under seal,

(e) that the information, after being sealed, be opened only by order of the Executive Director and/or Commission,

(f) that a trade secret or other confidential research, development, or commercial information not be disclosed, or be disclosed only in a designated way.

2. In determining whether "good cause" has been shown, the Executive Director or Reviewer shall consider whether the information sought is material to the demonstration of compliance with the review criteria and standards applicable to proceeding under review, and whether the production of such information is likely to cause annoyance, embarrassment, oppression, undue burden or expense, or unwarranted delay in the pending review which gave rise to the request.

3. Order. If the motion for a protective order is denied in whole or in part, the Executive Director or Reviewer may, on such terms and conditions as are just, order that the party or person provide the information.

4. Any motion filed under this Subsection, and any appeal thereof, shall stay the time period to provide the information that is the subject of the motion until and unless a ruling is issued that requires the production. Any ruling under this Subsection shall provide a time period for the production.

5. A movant, or any party or interested party in a contested or comparative review, may request reconsideration of a decision issued by the Executive Director or Reviewer by the Chair in response to a motion under this Subsection. A request for reconsideration shall stay any ruling issued under this Subsection.

6. For the purposes of this Subsection, any person, agency, or entity who is authorized to receive information under "seal" shall maintain the information using reasonably secure methods designed to limit the likelihood of disclosure of the information to any person not expressly authorized to receive the information by the order. Information provided under seal shall not be posted on the Commission website, and shall not be made available to persons not authorized by the order unless the Executive Director or Chair determines such production is required by statute, court order, or compulsory process and provides notice and an opportunity to object and/or intervene to the affected person(s)."

Several of the Proposed Regulations continue to give the Commission wide latitude to request information beyond that strictly required by the applicable review standards and criteria. UMMS has not proposed specific comments on these portions of the Proposed Regulations because its request for a protective order procedure would address this concern and provide an appropriate balance between liberal ability to request information by the Commission and its staff, and a party's rights to privacy and protection from undue burden in certain situations. However, should that proposal be rejected, UMMS has serious concern with any provision permitting the Commission or its staff to request information, and to condition an applicant's compliance with the regulations and the continued review of its request, where those requests are not limited to issues material to the person's demonstration of a review standard or criteria.

B. Provide Automatic or Deemed Approvals when Certain Conditions are Satisfied

UMMS proposes to add automatic or deemed approvals for Commission review of certain types of projects when all required conditions are satisfied and the Commission or Commission Staff has not acted on an application within a particular time frame. These proposed "deemed approvals" are similar to the amendment to MARYLAND CODE, HEALTH-GENERAL § 19-126(i) that went into effect October 1, 2019, which provides that a CON filed after October 1, 2019, shall be "deemed approved" if it is uncontested and final action by the Commission does not occur within 120 days after the CON is docketed. They are also in line with the Commission's Proposed Regulation .03A(2), which provides for automatic issuance of determinations of coverage for acquisitions of a health care facility if the Commission has not provided a determination within a 30-day time frame. Given that the Maryland General Assembly has found it appropriate to provide a "deemed approval" for a CON application if certain conditions are met, it is appropriate that "deemed approvals" should also apply to more streamlined and less complex filings than CON applications. Providing a "deemed approval" upon a certain date when an applicant has satisfied required conditions will balance the interests of the Commission in timely processing filings on its docket and applicants' interests in receiving timely determinations. Delays in receipt of project decisions can hamper applicants' efforts to resolve important patient access and care issues. Additional certainty around the timing of receipt of decisions from the Commission will support improved strategic and financial planning for applicants' key initiatives.

C. Require that Filings and Notices be Published to the Commission's Website

Government websites have become the most effective and helpful method of informing the public of the decisions and activities within government agencies. UMMS proposes that the Commission consistently adopt throughout its procedural regulations a requirement that any notices or filings that are available to the public be posted on the Commission's website within a specified time frame, in addition to posting notice of these filings in the Maryland Register and in newspapers in affected jurisdictions. This will consistently allow applicants and potentially affected parties a means to access any relevant filings and notices.

D. Refer to a Corresponding State Health Plan Chapter for Substantially Similar Requirements Rather than Restating them in the Procedural Regulations

In those sections of the procedural regulations that cover substantially similar requirements as contained in a relevant State Health Plan chapter, UMMS proposes that

the Commission cross-reference or incorporate by reference the relevant State Health Plan requirements, rather than restating them in the procedural regulations. The Commission updates the State Health Plan chapters with greater frequency than the procedural regulations. Restating material in the procedural regulations that is already set forth in a particular State Health Plan chapter creates a likelihood that the Commission may amend the State Health chapter at a later date without updating the corresponding procedural regulation, which creates confusion and uncertainty when there are multiple, varying rules that apply to a given issue. The State Health Plan chapters tend to contain more specific requirements than the procedural regulations. Thus, without duplication, the provisions of the procedural regulations should be more general and refer to specific requirements in applicable State Health Plan chapters. In the event the procedural regulations and a State Health Plan chapter contain different definitions of the same term, which should be avoided, UMMS proposes that the State Health Plan chapter definition would govern.

E. *Right to Oral Argument*

The right to request and/or present oral argument has been removed from several procedures in the Proposed Regulations. To promote advocacy on important issues, which advances sound decision-making by the Commission, UMMS urges the Commission to continue to permit oral argument in all instances where permitted by the existing regulations. The Commission is charged with making decisions that have significant financial and operational impact on health care providers and on Marylanders' access to care. Written filings are typically presented to the Commission by Commission Staff or a Reviewer, who necessarily has taken a position on the matter. A party should not be deprived of the opportunity to provide persuasive oral argument regarding its position on a request before the Commission.

F. Extension of Progress Reports, Obligation of Capital, and Post-Approval Project Changes to Projects Not Subject to CON Review.

Under the current procedural regulations, projects that do not require CON approval, including those that are expressly not subject to CON review as set forth in MARYLAND CODE, HEALTH-GENERAL § 19-120, are non-covered projects pursuant to existing regulation .03, or are otherwise exempt pursuant to existing Regulation .04, are not subject to required progress reports, a schedule requiring an obligation of capital, or post-approval project changes. Under the Proposed Regulations, all projects that have "other Commission approval" are subject to the procedural regulations governing progress reports, commitment of capital, and post-approval project changes. *See* Proposed Regulations .12B; .12C; .17A; .17B; and .17C. The Proposed Regulations refer to "other Commission approvals" and "a holder [of a Commission] approval." As described below, UMMS suggests that the proposed definition of "holder" be limited to a person or entity that has received CON approval from the Commission. Because

exceptions from CON review under Regulation .03 and exemptions from CON review under Regulation .04 are intended to be a more streamlined and less burdensome process than CON review, projects approved under Proposed Regulations .03 and .04 should be removed from the purview of Proposed Regulations .12B, .12C, .17A, .17B, and .17C. Proposed Regulations .12A, .12E-G, and .18 should provide the Commission with adequate oversight as to the implementation of a project excepted from CON review under Proposed Regulation .03 or exempted from CON review under Proposed Regulation .04.

II. Comments on Specific Proposed Regulations

A. Regulation .01, Definitions

1. "Adversely Affected"

UMMS supports the proposed changes to the definition of adversely affected that will require persons authorized to provide the same service in the same planning region to also demonstrate that approval of the application would either materially affect the quality of care at an existing facility or result in a substantial depletion of personnel or other resources at the facility to meet the definition of adversely affected. UMMS agrees that a more stringent threshold to demonstrate an adverse effect is appropriate for purposes of determining whether a person may qualify as an interested party in the review. UMMS, however, suggests further limiting this definition to ensure the appropriate geographic scope for potential interested parties. In particular, UMMS proposes that the Commission limit the categories of persons who may be considered "adversely affected" due to their provision of the same services as an applicant to those persons whose existing facilities are located in the same planning region as the proposed project. Allowing persons with facilities in contiguous planning regions to also demonstrate adverse effect under this definition creates an overly broad geographic scope for potential interested parties.

UMMS also proposes that the Commission clarify that the provision of the "same services" means the same "medical services," as that term is defined in Proposed Regulation .01B(38). Providing this level of specificity allows applicants and potential interested parties to better understand who may request participation in a review and avoids unnecessary confusion as to whether a proposed project will offer the same services as an existing facility in a particular region.

In light of these comments, UMMS suggests the following changes to Proposed Regulation .01B(2):

"(2) "Adversely affected", for purposes of determining interested party status in a

Certificate of Need review, as defined in §B(19) of this regulation, means that a person:

(a) Is authorized to provide the same medical service, as defined in COMAR 10.24.01.01B(3), as the applicant, in the same planning region, ~~or contiguous planning region if the proposed new facility or service could reasonably provide services to residents in the contiguous area~~, and can demonstrate that the approval of the application:

(i) Would materially affect the quality of care at a health care facility that the person operates, such as by causing a reduction in the volume of services when volume is linked to maintaining quality of care; or

(ii) Would result in a substantial depletion of essential personnel or other resources at a health care facility that the person operates; or

(b) Can demonstrate to the reviewer that a health care facility operated by the person could suffer a potentially detrimental impact from the approval of a project before the Commission, in an issue area over which the Commission has jurisdiction, such that the reviewer, in the reviewer's sole discretion, determines that the person should be qualified as an interested party in the review."

2. "Affected Public"

In accordance with UMMS' comments in Section II.D.3 below, UMMS proposes that the term "affected public" referenced in Regulation .04C(3) be defined as follows:

"(#) 'Affected public' means a person recognized by the Executive Director as the affected public and may include: (a) a person residing in the jurisdiction where the proposed project will be located who can demonstrate to the Executive Director that it meets the definition of adversely affected by approval of the proposed exemption project; or (b) a person residing in the county where the proposed project is located that can demonstrate a concrete and particular adverse effect on the public that is actual or imminent if the proposed project is approved."

3. "Bed capacity"

To align with the definition in the State Health Plan chapter on Acute Care Hospitals, UMMS propose that "bed capacity" be defined as follows:

"(7) 'Bed capacity' ~~or 'physical bed capacity'~~ means the ~~total~~ number of beds that a health care facility can physically accommodate for a medical service, including beds that are available for use and those that could be physically set up in space appropriate for licensed care as admissions might warrant. For a hospital, bed capacity does not include emergency department treatment space, dedicated observation beds, or other space dedicated for non-medical services. ~~and staff in space designed for and licensable for use by patients requiring an overnight stay at the facility.~~"

4. "Holder"

Proposed Regulations .12B; .12C; .17A; .17B; and .17C require a "holder" of any project receiving Commission approval to submit semi-annual progress reports, obligate capital for a project under a defined schedule, and obtain Commission approval for certain project changes. Because exceptions from CON review under Regulation .03 and exemptions from CON review under Regulation .04 are intended to be a more streamlined and less burdensome process than CON review, projects approved by the Commission within the scope of Proposed Regulations .03 and .04 should be removed

from the purview of Proposed Regulations .12B, .12C, .17A, .17B, and .17C. Proposed Regulations .12A, .12E-G, and .18 should provide the Commission with adequate oversight as to the implementation of a project excepted from CON review under Proposed Regulation .03 or exempted from CON review under Proposed Regulation .04. Accordingly the definition of "holder" should be limited to a person or entity that has received CON approval from the Commission for a proposed project as follows:

> "(27) "Holder" means the applicant or applicants to whom the Commission awarded a Certificate of Need~~, an exemption from Certificate of Need, or other approval for a project that has not received first use approval nor, if necessary, a license from the Department for that project~~."

5. "Interested Party"

UMMS supports the removal of certain third-party payors from the definition of "interested party" in Proposed Regulation .01B(31). This modification aligns the Proposed Regulation more closely with the enabling statute, MARYLAND. CODE, HEALTH-GENERAL § 19-126, which does not require inclusion of third-party payors in the definition of "interested party."

UMMS also suggests adding additional text to the definition of "interested party" that cross-references the procedural requirements to become an interested party pursuant to Regulation .08F. Under Regulation .08F, a person seeking interested party status must file written comments on an application within 30 days of docketing. Those comments must include sufficient information to establish that the person meets the definition of "interested party" as set forth in Regulation .01B. Regulation .08F further require persons opposing an application to state with particularity the State Health Plan standards and/or review criteria that the person believes the applicant has not met. UMMS notes that historically, the comments filed by persons seeking interested party status have not always satisfied the elements of Regulation .08F, such as by failing to state with particularity how the applicant has failed to meet certain criteria. In certain cases, however, persons have nevertheless been recognized as interested parties to the review. To ensure that all regulatory requirements to obtain interested party status are satisfied, including that a person falls into one of the categories set forth in Regulation .01B(31) and has complied with the procedural elements in Regulation .08F governing interested party comments, UMMS proposes to cross-reference Regulation .08F in the definition of interested party.

UMMS proposes the following modifications to Proposed Regulation .01B(31):

"(31) 'Interested party' means a person recognized by a reviewer as an interested party, including:

(a) Any applicant who has submitted a competing application in a comparative review;

(b) The staff of the Commission.

(c) A local health department in the jurisdiction or, in the case of regional medical services, in the planning region, in which the proposed facility or medical service is to be offered;

(d) In the review of a replacement acute general hospital project proposed by or on behalf of a regional health system that serves multiple contiguous jurisdictions, a jurisdiction within the region served by the regional health system that does not contain the proposed replacement acute general hospital project; and

(e) A person who has demonstrated to the Reviewer that it meets the definition of adversely affected by the approval of a proposed project.

(f) Notwithstanding the foregoing, a person may not be recognized as an interested party until and unless such person has submitted written comments in accordance with .08F."

6. "Merged Asset System"

Proposed Regulation .01B(39) proposes to define "merged asset system" as "an entity comprised of one or more regulated health care facilities under common ownership." Although this term is used throughout the Commission's existing regulations, it is not defined in the Commission's existing regulations, nor in its enabling statute. Several of the Commission's Proposed Regulations describe facilities belonging to a "merged asset system" as being "owned or controlled" by a merged asset system, such as Proposed Regulations .02A(2)(b), .02A(5)(a), .03E, and .04A(2).

For internal consistency within the Commission's existing regulations and in order to capture all those facilities that may properly rely upon the "merged asset system" rules under the Commission's existing regulations, UMMS proposes the following modification to Proposed Regulation .01B(39):

"(39) 'Merged asset system' is an entity comprised of one or more regulated health care facilities under common ownership or control."

7. "Partial Closure"

The Commission's enabling statute and the Proposed Regulations use the term "partial closure" or "partial closing" but these terms are not defined. *See, e.g.*, MARYLAND CODE, HEALTH-GENERAL § 19-120(l)(1)-(6), Proposed Regulation 10.24.01.03C; Proposed Regulation 10.24.01.04D. Although not defined in its current Proposed Regulations, the Commission has historically interpreted a partial closure as being a facility's permanent closure of a medical service line. In order to clarify what constitutes a "partial closure" implicating a facility's notice and public hearing obligations under the Commission's regulations, UMMS suggests the Commission adopt the following definition in Proposed Regulation .01B:

"(#) 'Partial Closure' means when a facility permanently closes or decommissions a medical service as defined in Regulation .01B."

8. "Participating Entity"

Proposed Regulation .01B(43) defines "participating entity." In accordance with the comments in Section II.A.5 above, UMMS proposes that the definition of "participating entity" be revised to cross-reference the procedural requirements governing participating entity status in Regulation .08F. To obtain participating entity status, persons must not only fall into one of the categories set forth in Regulation .01B(43), but must also file comments that state with particularity the State Health Plan standards or review criteria that the person believes the applicant has not met. To ensure that all regulatory requirements to obtain participating entity status are satisfied, UMMS proposes to cross-reference Regulation .08F in the definition of participating entity.

UMMS also proposes to modify subsection (a) of Proposed Regulation .01B(43) regarding the types of third-party payors that may qualify as participating entities. As set forth in the Insurance Article of the Maryland Code, to engage in the insurance business in the State of Maryland, an insurer generally must hold a valid certificate of authority issued by the Commissioner. MARYLAND. CODE, INSURANCE § 1-101. Instead of listing multiple examples of third-party payors in a non-exhaustive list, which may change over time, UMMS proposes to simply this definition by stating that those third-party payors authorized to engage in the insurance business may qualify as participating entities, provided they comply with all other applicable requirements to obtain such status.

UMMS proposes the following modifications to the definition of participating entity in Proposed Regulation .01B(43):

"(43) 'Participating entity' means a person recognized by the Executive Director as a participating entity and may include:

(a) A third-party payor ~~including~~ that holds a certificate of authority in Maryland or is otherwise authorized to engage in the insurance business pursuant to the Insurance Article of the Maryland Code:

~~(i) An insurer or nonprofit health service plan that holds a certificate of authority and provides health insurance policies or contracts in Maryland;~~

~~(ii) A health maintenance organization that holds a certificate of authority in Maryland;~~

~~(iii) A union that is providing a health plan to union members on behalf of the employer in a jurisdiction in which the proposed project will be located or from which an existing health care facility seeks to relocate;~~

~~(iv) A pharmacy benefit manager; and~~

~~(v) A self-insured employer offering health benefits through the Employer Retirement Insurance Security Act of 1974.~~

(b) A municipality where the proposed project will be located or from which an existing health care facility seeks to relocate; or

(c) In the case of a hospital project, a local health department in a county that borders a county in which a proposed facility or medical service will be

located.

(d) Notwithstanding the foregoing, a person may not be recognized as a participating entity until and unless such person has submitted written comments in accordance with .08F."

9. "Primary Service Area"

Proposed Regulation .01B(47) proposes a definition of "primary service area" that largely mirrors the definition of that term in the Acute Care Hospital State Health Plan chapter, but differs slightly. UMMS notes that the term "primary service area" is only used in the Acute Care Hospital State Health Plan chapter, whereas other State Health Plan chapters either use the term "service area" or do not define a specific area at all. The Commission's enabling statute and the Proposed Regulations, however, use the term "primary service area" in reference to relocation of "health care facilities" and these rules are not intended to be specifically tied to acute care hospitals. *See, e.g.*, MARYLAND CODE, HEALTH-GENERAL § 19-120(g)(2)(iii), Proposed Regulation 10.24.01.03E(1); Proposed Regulation 10.24.01.04A(2)(a).

To avoid a conflict in the methodology for determining a service area between the procedural regulations and the applicable State Health Plan chapter, UMMS proposes to amend the definition of "Primary service area" as follows:

"(47) Primary service area has the meaning set forth in COMAR 10.24.10.06. ~~means:~~

~~(a) The Maryland postal ZIP code areas from which the first 60 percent of a hospital's patient discharges originate during the most recent 12-month period, where:~~

~~(i) The discharges from each ZIP code area are ordered from largest to smallest number of discharges; and~~

~~(ii) Two or more ZIP code areas having the same numbers of discharges are ordered from the largest to smallest based on the percentage of the hospital's discharges originating from the ZIP code area in the most recent 12-month period [are both included in the primary service area];~~

~~(b) Point ZIP codes physically within any of the ZIP code areas designated in §B(47)(a) of this regulation;~~

~~(c) Maryland ZIP code areas physically contiguous to any of the ZIP codes designated in §B(47)(a) of this regulation that provided 50 percent or more of their discharges to the hospital in the most recent 12-month period; and~~

(d) ~~For a merged asset system, the ZIP code areas that are tabulated separately for each hospital, and all ZIP code areas identified for each hospital which are included in the primary service area of the merged asset system.~~"

10. "Service Area"

In accordance with UMMS' comments in Section II.C.2 and II.D.1 below, UMMS proposes to add a definition of "service area" as follows:

"(#) 'Service area' shall have the definition set forth in the applicable chapter of the State Health Plan."

11. "Contested Review"

Because a contested review imposes additional procedures in a review, UMMS proposes to add a definition of "contested review" in order to confirm existing practice as to when a review is considered to be contested.

"(#) 'Contested Review' means a review in which a person has been recognized by a Reviewer as an interested party. If a person is no longer deemed an interested party consistent with these regulations, the review shall cease to be a contested review."

B. Regulation .02, Coverage

1. Coverage Generally

Proposed Regulation .02A provides, "[e]xcept as provided in Regulations .03, .04 and .05 of this chapter, a CON is required before: . . ." The Commission's procedural regulations have largely not been updated since 2005, despite interim statutory changes. Thus, the procedural regulations have not been kept current with statutory changes providing for approval of projects that are not subject to CON review. As a result, UMMS suggests that Proposed Regulation .02A be amended to provide flexibility for statutory changes that may take place prior to regulatory amendments and that Proposed Section .02A be amended to state:

"A. Except as provided in Regulations .03, .04 and .05 of this chapter or as otherwise provided by law, a CON is required before: [. . .]"

2. Type or Scope of Health Care Services

Proposed Regulation .02A(4)(c) states that a CON is required before "[t]he type or scope of any health care service offered by a health care facility is changed, and the change: (c) Establishes a new home health agency, general hospice care program, or freestanding ambulatory surgical facility[.]" The term "freestanding ambulatory surgical facility," although appearing in the Proposed Regulation, is not defined. Thus, UMMS suggests that the Proposed Regulation be amended to delete reference to "freestanding" such that existing regulation .02A(4)(c) would read:

"(c) Establishes a new home health agency, general hospice care program, or ~~freestanding~~ an ambulatory surgical facility[.]"

C. Regulation .03, Non-Coverage

1. Sale of Temporarily Delicensed Bed Capacity – Regulation .03D

Proposed Regulation .03D provides the rules for temporary delicensure of a licensed and operating health care facility or that facility's licensed bed capacity, and allows a facility to retain temporary delicensed bed capacity on the facility's inventory for up to one year if certain conditions are satisfied. Section D(5) of this Proposed Regulation requires that "[n]o fewer than 30 days before the end of the 1-year or other applicable [temporary delicensure] period, a health care facility that has temporarily

delicensed bed capacity or its entire facility shall notify the Commission that" it will take one of the actions permitted under this section. Subpart D(5)(e) provides one option to:

> "(e) Execute a binding contract to transfer ownership of the previously licensed bed capacity, contingent on the filing within 30 days of a letter of intent to apply for CON approval, or other applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter if required, to relocate the bed capacity[.]"

However, Proposed Regulation .07A(3) specifies that "[a] letter of intent [for a prospective applicant for CON review] shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no applicable review schedule has been published, a letter of intent may be submitted at any time."

Proposed Regulation .03D(5)(e)'s requirement to file a CON letter of intent within 30 days of executing the sales contract to sell the temporarily delicensed bed capacity sometimes creates a conflict with Proposed Regulation .07A(3)'s requirement to file a letter of intent in accordance with the review schedule published by the Commission. In addition, the 30-day time frame provided in this rule to file a letter of intent and subsequent CON application or prepare a notice of intent to seek an exemption from CON review is very condensed for preparation of CON applications or exemption requests which are fairly extensive filings. The time pressure created by this rule may result in incomplete or rushed filings, which is not in the interest of the parties or the Commission.

UMMS suggests Proposed Regulation .03D(5)(e) be modified to eliminate the internal conflict in the regulations and provide a more reasonable time frame for parties to submit the applicable filing following execution of a sales contract, as follows:

> "(e) Execute a binding contract to transfer ownership of the previously licensed bed capacity, contingent on the filing within ~~30~~ 90 days for those filings not subject to a published review cycle, or upon the Commission's next published review schedule in accordance with regulation .07 of a letter of intent to apply for CON approval, or other applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter if required, to relocate the bed capacity[.]"

2. Relocation of facilities owned or controlled by a merged asset system –Regulation .03E

As noted in Section II.A.10 regarding the defined terms "primary service area" and "service area," the Commission's enabling statute and Proposed Regulations .03E and .04A(2) use the term "primary service area" – a definition referring solely to hospitals – in reference to relocation of other "health care facilities" and these rules were not intended to be limited to relocation of hospitals. UMMS proposes the following modifications to Proposed Regulation .03E to clarify that non-hospital facilities may relocate using this rule:

> "E. A CON is not required to relocate an existing health care facility owned or controlled by a merged asset system, if:
>
> (1) The proposed relocation is to a site in: (a) the primary service area, as defined in regulation .01B, of the acute care hospital to be relocated and the relocation is not across jurisdictional boundaries; or (b) in the service area of the non-hospital health care facility to be relocated, ~~as~~ to the extent defined in the State Health Plan, and the relocation is not across jurisdictional boundaries;"

3. Non-Hospital Health Care Facilities owned by a Health Maintenance Organization – Regulation .03G

Proposed Regulation.03G permits a health maintenance organization ("HMO") to undertake a health care project otherwise subject to CON review if "[a]t least 90% of the patients who will receive health care services from the project are enrolled in the health maintenance organization" without obtaining a CON. While UMMS recognizes that the Proposed Regulation is in accordance with MARYLAND CODE, HEALTH-GENERAL § 19-121(b)(ii) and Proposed Regulation .02E, the proposed procedural regulations do not address how or when the 90% threshold of HMO health care facility enrollment will be assessed or overseen.

As a result, an HMO, after constructing a health care facility otherwise subject to CON review could potentially serve greater than 10% of non-HMO enrollees. HMOs would thereby have a competitive advantage over non-HMOs in opening health care facilities otherwise subject to CON review. UMMS proposes that the Commission staff

annually survey the percentage of patients seen at an HMO facility exempt from CON review under Proposed Regulation .03G to ensure compliance with the statutory and regulatory threshold for health care facility patient membership in the HMO. Thus, UMMS proposes adding the following regulation at .03G(d):

> "(d) Notwithstanding the foregoing, any health care facility built, developed, or established following approval under this subsection shall be subject to review at least annually by the Commission to ensure at least 90% of patients receiving treatment at the health care facility in the prior calendar year are enrolled in the health maintenance organization. If less than 90% of patients treated at a health care facility built, developed, or established following approval under this subsection in a calendar year are members of the health maintenance organization, the health maintenance organization shall obtain CON approval in order to continue operating the health care facility in accordance with Regulation .02E."

4. Hospital Capital Expenditures in Excess of the Hospital Capital Threshold – Regulation 3J

Proposed Regulation .03J(2) states that "[a]fter consultation with the Health Services Cost Review Commission, the Commission shall issue a determination *whether CON review is* required within 45 days after it receives the information specified in this section." (emphasis added). Proposed Regulation .03J(3) also adds a new provision permitting the Commission Staff to attach conditions to a determination of coverage regarding a pledge project.

The Commission's enabling statute permits the Commission, after consultation with the Health Services Cost Review Commission, to determine "the relevant information to be submitted by the hospital" in order to make a determination under Proposed Regulation .03J that the project "[d]oes not require, over the entire period or schedule of debt service associated with the project, a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project[.]" MARYLAND CODE, HEALTH-GENERAL § 19-120(k)(6)(viii). Although the enabling statute provides for the imposition of conditions on a CON decision, no such authority is provided for projects not subject to CON review. See *Id.* at 19-126(d)(12). Rather, the authority of the Commission to regulate such projects, as provided by the

Legislature, is that prescribed by the enabling statute. Accordingly, if an applicant has complied with the Commission's requirements set forth at Proposed Regulation .03J, the Commission should not have discretion to require CON review unless it finds that the project will require a total cumulative increase in patient charges or rates in excess of $1.5 million, nor the authority to attach conditions to its determination of coverage. UMMS proposes the following modifications to Proposed Regulation .03J:

"(2) After consultation with the Health Services Cost Review Commission, the Commission shall issue a determination ~~whether~~ that CON review is not required within 45 days after it receives the information specified in this section.

. . .

~~(3) Commission staff shall issue a determination that either CON review is not required, with or without conditions, or that CON review is required for stated reasons~~."

D. Regulation .04, Exemptions from CON Review

1. Exemptions from CON Review – Regulation .04A(2)

In accordance with UMMS' comments in Sections II.A.10 and II.C.2 above regarding the defined terms "primary service area" and "service area" and clarifying the application of Proposed Regulations .03E and .04A(2) to the relocation of non-hospital facilities, UMMS proposes to amend Regulation .04A(2) as follows:

"(2) Relocation of an existing health care facility owned or controlled by a merged asset system, if:

(a) The relocation is to a site: (i) outside the primary service area, as defined in regulation .01B, for an acute care hospital to be relocated but within the primary service area of the merged asset system; or (ii) outside the ~~primary~~ service area, as defined in regulation .01B, of the health care facility to be relocated but within the primary service area of the merged asset system;"

2. Changes in Bed Capacity Due to a Merger or Consolidation – Regulation .04A(3)

Proposed Regulation .04A(3) provides an exemption for "[a] change in the bed capacity of an existing health care facility pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a non-health-related use, except as provided in Regulation .03I of this chapter[.]"[1] However, the Proposed Regulations propose to add new language in Section .03F(1)(b) providing that a "a CON is not required to increase or decrease bed capacity if . . . [t]he change is proposed pursuant to a merger or consolidation between health care facilities[.]"

UMMS supports making these types of bed changes occurring as part of a merger or consolidation subject to the non-coverage rule rather than the exemption process and this change is consistent with the enabling statute language at MARYLAND CODE, HEALTH-GENERAL § 19-120(h)(2)(iii). Based on the new language proposed in Proposed Regulation .03F(1)(b), the exemption provided in Proposed Regulation .04A(3) is now duplicative and creates confusion about whether these types of bed changes are subject to non-coverage or the exemption process. UMMS proposes the Commission eliminate the exemption at .04A(3) since changes in bed capacity pursuant to a merger and consolidation are now included under Proposed Regulation .03F(1)(b), and modify in Proposed Regulation .03F(1)(b) to include language consistent with the enabling Statute at MARYLAND CODE, HEALTH-GENERAL § 19-120(h)(2)(iii) as follows:

> "(b) The change is proposed pursuant to a merger or consolidation between health care facilities, or conversion of a health care facility or part of a facility to a nonhealth-related use, the ~~hospital~~ health care facility notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services, and the Commission finds that the change:
>
> ~~(c)~~ (i) Is not inconsistent with the State Health Plan or the institution-specific plan developed by the Commission;

[1] The reference to Section .03I seems to be an error as that section covers Religious Orders seeking licensure as comprehensive care facilities and has nothing to do with changes in bed capacity.

(ii) Will result in the delivery of more efficient and effective health care services; and

(iii) Is in the public interest."

3. Solicitation of Comments on Exemption Projects from the "Affected Public" – Regulation .04C(3)

Proposed Regulation .04C(3) states that "The Commission shall solicit comment from the *affected public*, in evaluating whether the action or project proposed for exemption from CON review is in the public interest." (emphasis added). Subsections .04C(1)-(2) provide the process through which the Commission will provide notice to and solicit comments from the public, which involves publishing notice in at least one newspaper of general circulation in the affected area, in the next available issue of the *Maryland Register*, and on the Commission's website, and mailing notice to elected public officials in the jurisdiction in which the exemption project is proposed. This process appears to create quasi-interested party status for whomever decides they may be "affected" by the proposed CON exemption project.

MARYLAND CODE, HEALTH-GENERAL § 19-126(d)(7) provides the clear right for any "interested party" to "submit written comments on [a CON] application in accordance with the procedural regulations adopted by the Commission." It also clearly defines who may qualify as an "interested party" in a CON review, including "any other person who can demonstrate that the person would be adversely affected by the decision of the Commission on the application[.]" *Id.* at 19-126(d)(8). In contrast, the Maryland General Assembly did not provide any interested party rights, including the right to submit written comments, in the CON exemption process.

This proposed quasi-interested party status could greatly increase the time and expense of the review of exemption projects, and it could allow a person without any real or immediate impact from a proposed project to submit comments. When a person submits comments in the CON exemption process, the Commission Staff must take them under consideration and the applicant must respond to the comments or it may adversely affect the project's review.

UMMS proposes that the Commission eliminate Proposed Regulation .04C(3). In the alternative, the Commission should at a minimum: (1) define which parties qualify as the "affected public," (2) specify the time frame for submission of written comments to be no more than 10 days after publication of notice in the *Maryland Register* so as not to delay review of the exemption request, and (3) clarify that such parties do not have any "interested party" rights under its procedural regulations, but the Commission may, in its

discretion, consider such comments when assessing whether the exemption project is in the public interest. UMMS has proposed a definition of "affected public" in Section II.A.1 above, and also suggests that Proposed Regulation .04C(3) be modified as follows:

> "(3) The Commission shall solicit comment from the affected public by providing an explanation in its published notice in the *Maryland Register* that a person who meets the definition of 'affected public' in Regulation .01B of this chapter may submit written comments on the exemption project within 10 days of the published notice. The written comments may include information the affected public wishes the Commission to consider regarding the project's adverse effect on the public. A person recognized by the Executive Director as qualifying as the 'affected public' as defined in Regulation .01B does not have interested party or participating entity status and has no right to judicial review of the final Commission decision. The Commission may, in its discretion, consider such comments in evaluating whether the action or project proposed for exemption from CON review is in the public interest."

4. Public Hearing Requirements for Closures and Partial Closures – Regulations .03C and .04D

MARYLAND CODE, HEALTH-GENERAL § 19-120(l)(2) requires hospitals to hold a public informational hearing after filing a notice of closure or partial closure with the Commission and Section 19-120(l)(3) states that "[t]he Commission may require a health care facility other than a hospital . . . that files a notice of its proposed closing or partial closing to hold a public informational hearing in the county where the health care facility is located." Proposed Regulation .03C(2) further specifies that hospitals that file a notice of closure or hospitals in counties with fewer than three acute general hospitals that file a notice of partial closing must hold a public informational hearing, and Proposed Regulation .03C(3) states that "[t]he Commission may require a health care facility not covered by § C(2) to hold a public information hearing[.]" UMMS has proposed a definition of "partial closure" in Section II.A.10 to clarify when a facility's notice and

public hearing obligations are implicated under the Commission's Proposed Regulations .03C and .04D.

The Commission also has discretion over whether to require health care facilities other than hospitals to hold a public hearing prior to their closure or partial closure. Similar to the partial closure of an underutilized medical service line at a hospital, closure or partial closure of underutilized health care facilities may be unlikely to affect or minimally affect the public and the requirement to hold a public informational hearing may be superfluous in these circumstances. Even if the Commission determines that it is beneficial to hold a public hearing for a partial closure of a hospital or the closure or partial closure of another health care facility, Proposed Regulation .04D(3) currently provides a one-size-fits-all set of requirements that apply to all public hearings held for closure or partial closure of a facility. The requirements are not only inapplicable to closure of a home health agency, for example, by requiring the facility to address the "plan for transitioning acute care services previously provided by the hospital" but also the requirement to provide a written summary of the hearing to the Governor and numerous other officials is excessive and burdensome for the facility to prepare, and inconsequential for most of the officials receiving the written summary. The Commission should retain discretion to determine what information should be presented at these types of public hearings and whether a written summary needs to be provided to any other parties in order to tailor a process that is more appropriate for the types of closures that are less likely to have a significant effect on the public. UMMS proposes to add a new section .04D(4) providing the Commission Staff the necessary flexibility to prescribe the requirements for public hearings that it determines are needed for these other types of closures or partial closures:

> "(4) Hospitals and health care facilities required to hold a public informational hearing in accordance with Maryland Code, Health-General § 19-120(l)(3) and Regulation .03C(2) of this chapter shall hold the public informational hearing at the health care facility, or if that is not feasible, at a public meeting area near the health care facility. The hospital or health care facility shall consult with the Commission Staff regarding the information that will be addressed at the public hearing, and whether a written summary of the hearing will be required to be provided following the hearing, and if so, to which individuals."

Proposed Regulation .04D(3)(c) requires hospitals to "identify to the public the names of the senior management and Board of Directors attending" the public informational hearing. For a variety of reasons, hospitals should not be required to publicly identify specific leaders who will attend the hearing. It would be more appropriate to provide names of its attendees to the Commission Staff and simply require the hospital to ensure that appropriate members of its leadership team are available to address questions at the public hearing. UMMS proposes Regulation .04D(3)(c) be modified as follows:

"(c) The hospital shall identify to the Commission Staff ~~the public~~ the names of the senior management and Board of Directors attending the meeting, and shall ensure members of senior management are available at the public hearing to address questions and comments[.]"

5. Deemed Approval of Exemption Projects When the Applicant's Conditions are Satisfied and the Statutory Time Frame for Approval has Passed – Regulation .04E

The Commission's enabling statute provides that exemptions from CON review shall be acted upon by the Commission within 45 days of receipt of the facility's notice. MARYLAND CODE, HEALTH-GENERAL § 19-120(j)(2)(iv)(3), (k)(6)(v)(2), (h)(2)(iii)(3). Proposed Regulation .04E incorporates this statutory time frame for the Commission's decision; however, in line with UMMS' comments in Section I.B, it should be amended to establish a status reporting requirement and a contingency if the Commission does not act within this required time frame. UMMS proposes Proposed Regulation .04E be amended to add new subparts (3) and (4), as follows:

"(3) For any exemption from CON review project which qualifies as exempt under §A for which a final Commission decision has not been issued within 45 days after it receives a complete notice of intent as required by §B, the Commission shall provide a status report at the next Commission meeting and any subsequent Commission meeting stating the reasons for the delay and the expected time frame for issuing its final decision.

(4) CON review is not required and the exemption request shall be deemed approved for any project which qualifies as exempt under §A, if final action by the Commission does not occur within 90 days after the facility or system has provided complete notice of intent as required by §B and has held a public hearing if required by §D of this regulation."

This suggested modification is modeled off the recent amendments to MARYLAND CODE, HEALTH-GENERAL § 19-126(i) that went into effect October 1, 2019, which provide that a CON filed after October 1, 2019, shall be "deemed approved" if it is uncontested and final action by the Commission does not occur within 120 days after the CON is docketed. In addition, it is similar to the Commission's changes to Proposed Regulation .03A(2) providing for automatic issuance of determinations of coverage for acquisitions of a health care facility if the Commission has not provided a determination within a 30-day time frame. Given that an exemption from CON review is intended to be a more streamlined, less complex filing than a CON application, a contingency of providing a deemed approval within 90 days, which is twice as long as the statutorily prescribed time frame, balances the interests of the Commission in timely processing filings on its docket with applicants' interests in receiving prompt determinations to move forward with important business initiatives.

Similarly, Proposed Regulation .04F(4) should be amended to incorporate the timeline for Commission action on exemption projects seeking to convert an acute general hospital to a freestanding medical facility ("FMF"), as provided in the enabling statute at MARYLAND CODE, HEALTH-GENERAL § 19-120(o)(3)(i)(6), and provide for status reports and deemed approvals if the Commission does not act within the required time frame. UMMS proposes the following modifications to Proposed Regulation .04F(4), as follows:

"(4)(a) The Commission may approve, approve with conditions, or deny the requested exemption within 60 days after it receives the complete notice of intent, if the facility or merged asset system seeking the exemption qualifies for exemption under §A and has provided the information required by the notice of intent and held a public informational hearing, in accordance with this regulation and COMAR 10.24.19.04C.

(b) For any exemption from CON review seeking establishment of a freestanding medical facility as a result of a conversion from a licensed acute general hospital, which qualifies as exempt under §A for which a final Commission decision has not been issued within 60 days after it receives a complete notice of intent as required by §B, the Commission shall provide a status report at the next Commission meeting and any subsequent Commission meeting stating the reasons for the delay and the expected time frame for issuing its final decision.

(c) CON review is not required and the exemption request for establishment of the freestanding medical facility shall be deemed approved for any project which qualifies as exempt under §A, if final action by the Commission does not occur within 120 days after the facility or system has provided the information required by the notice of intent and held a public informational hearing, in accordance with this regulation and COMAR 10.24.19.04C."

6. Exemption Holder Responsibilities and Withdrawal of an Approved Exemption – Regulation .04F(5)

Proposed Regulation .04F(5) should be amended to eliminate the language that an approved exemption project "maintain compliance with the requirements of the State Health Plan" or the exemption may be withdrawn by the Commission. The requirements at COMAR 10.24.19.04C within the State Health Plan Chapter for Freestanding Medical Facilities pertaining to an acute hospital conversion to an FMF relate to obligations or criteria that must be satisfied as part of the applicant's submission of notice and information to the Commission and to the obligation to hold a public hearing and provide a written summary of the same to various individuals, all of which must be completed prior to the Commission issuing its decision on the project. After the Commission has approved a CON exemption project, there are no continuing obligations or standards within COMAR 10.24.19.04C that an applicant must continue to satisfy other than conditions the Commission may place upon the original approval, and this language creates uncertainty for the exemption holder and seemingly could authorize the Commission's withdrawal of an exemption approval without an appropriate basis.

In addition, Proposed Regulation .04F(5) should be modified to provide an exemption project holder the same right as a CON project holder has in the Proposed Regulation .12A(4) to request reasonable modifications to their FMF conversion timeline. Failure to comply with the original proposed FMF timeline for conversion should not result in withdrawal of the exemption given the time, expense, and stakeholder input that is required for an approved exemption to convert a hospital to an FMF and the many unknown events that may transpire after approval and before the planned conversion that could require changes in the timeline originally proposed by the exemption holder:

> "(5) Failure to maintain compliance ~~with the requirements of the State Health Plan,~~ with conditions on an exemption, or with the timeframe for completion of the conversion ~~shall~~ may result in withdrawal of the exemption issued by the Commission in accordance with Regulation .12. An exemption holder may request Commission Staff approval of a reasonable modification to the conversion timeline in accordance with Regulation .12A(4)."

E. Regulation .05, ASC Determinations of Coverage

Proposed Regulation .05 addresses determinations of coverage and data reporting for ambulatory surgery centers.

The State Health Plan chapter for General Surgical Services already addresses determinations of coverage for these facilities. *See* COMAR 10.24.11.04. Thus, there is regulatory duplication between the State Health Plan and the procedural regulations, which could lead to confusion and inconsistency, especially since the Commission periodically amends the State Health Plan but does not routinely amend the procedural regulations. UMMS proposes that the Commission eliminate Proposed Regulation .05A, and amend the State Health Plan to include any desired new language that is not already included in the State Health Plan.

For example, Proposed Regulation .05A(5), establishing a two-year expiration date for determinations of coverage, could be added to the State Health Plan, since the State Health Plan does not address timing. However, if that amendment is made, UMMS suggests that the Commission use the same project timing approach as in Proposed Regulation .12A, which would allow a party to propose a project implementation schedule that the Commission may approve, reject, or modify, rather than establish a hard deadline that cannot be changed regardless of the circumstances.

F. Regulation .07, Preapplication Procedures

1. Letter of Intent Prospective Applicants, Regulation .07A

At times, the legal entity that will be the licensee for a project has not been formed at the time that an applicant files a letter of intent. Given the delays in creating and registering entities that UMMS has experienced with the Maryland State Department of Assessment and Taxation, the existing regulations that permitted identification of a licensee not yet formed, and the apparent goal in the existing regulations of providing sufficient information to identify the intended licensee and ownership structure, UMMS recommends the following subpart be added following Proposed Regulation .07A(1) and that the subsequent provisions be renumbered accordingly:

> "(1) A prospective applicant for a Certificate of Need shall submit to the Center for Health Care Facilities Planning and Development a brief letter of intent, with a copy to each local health department in the health planning region. The Center for Health Care Facilities Planning and Development shall formally log all letters of intent upon receipt.
>
> (2) A prospective applicant identified in a letter of intent may be the person or persons who will be the licensee as specified in Health-General Article, §19-318 et seq., Annotated Code of Maryland. If the legal entity that will be the licensee has not yet been formed or finalized, a prospective applicant may identify the intended ownership and control of the licensee."

2. Letter of Intent Filing Dates, Regulation .07A

Proposed Regulation .07A(3) states that "[a] letter of intent shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no applicable review schedule has been published, a letter of intent may be submitted at any time." In some instances, the Commission's published review schedule or review frequency creates significant challenges for an applicant and a barrier to timely initiating important CON projects that may resolve access to care issues or provide other important services needed by the community. UMMS proposes regulation .07A(3) be modified to allow an applicant to submit a letter of intent outside of a required published review schedule where good

cause is shown, as follows:

"(3) A letter of intent shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no applicable review schedule has been published, a letter of intent may be submitted at any time. For projects subject to a published review schedule, an applicant may request that the Executive Director waive the required letter of intent filing date and allow filing upon another date with a showing of good cause."

G. Regulation .08, Procedure for Review of CON Applications

1. Submission of Application, .08B

Consistent with UMMS' comment in section II.F.1 above regarding formation of applicant entities, UMMS recommends the following subpart be added following Proposed Regulation .08B as subsection (1), and that the subsequent provisions be renumbered accordingly:

"(1) The application shall be filed on behalf of the intended licensee. If the legal entity that will be the licensee has not yet been formed or finalized, an applicant may identify the intended ownership and control of the licensee."

2. Completeness Review, extensions, .08C

UMMS proposes to modify Proposed Regulation .08C(7) to conform to existing practice, through which Staff liberally grant reasonable requests for extension.

"A. Completeness Review and Docketing.
…
(5) If an applicant fails to supply the required information within the specified time limit, staff may dismiss the application. Staff may, at its discretion, extend the response time for an applicant in a noncomparative review, or, with the consent of

all applicants, for an applicant in a comparative review, up to an additional ten business days, or more upon a demonstration of good cause for the additional extension."

3. Completeness Review, scope of requests for information during completeness, finality of dismissal, .08C

UMMS notes in General Comment IA, *supra*, its serious concerns regarding the scope of certain requests for information. UMMS further notes, consistent with those concerns, that Proposed Regulation .08C gives the Commission Staff wide latitude to request information beyond that required by the applicable review standards and criteria. UMMS has not proposed comments that would limit the scope of an initial inquiry under .08C because its request in General Comment IA for a procedure to seek protection from overly burdensome requests would address this concern. Should that proposal be rejected, UMMS notes here its objection to any provision permitting the Commission Staff to request information not material to the demonstration of compliance with a review standard or criteria without appropriate safeguards.

UMMS does propose a limit on subsequent requests for additional information after a first request has been made. UMMS is concerned that the length and scope of completeness review may at times extend beyond reasonable time periods. UMMS has, on occasion, received duplicative requests, requests that sought information clearly provided in the application, or requests on issues not touched on by prior request for information. Such an extended process imposes considerable costs on UMMS as it requires a shift in the focus of clinical and planning team members, as well as consultants, at interrupted intervals. In addition to the cost of resources and time in responding these requests, the process impedes the efficient review of an application, and ultimately the completion of the project. UMMS encourages a procedural change to require that all requests for additional information raised prior to docketing be asked in a single written request, except where responding to or seeking additional information regarding information provided in response to the first request. Such a provision would streamline the completeness review process. Moreover, this will not impede the ability to request information after docketing beyond that required to make an application complete.

UMMS further proposes an outside time limit for Commission Staff to review an application for completeness. This proposal is consistent with the legislature's intent to improve the review period of CON applications, as reflected by recent statutory amendments to Md. Code, Health-Gen. § 19-126. Coupled with the regulations that impose outside time limits on review of an application after docketing, an outside time

limit on completeness review should improve efficiency of CON review and parties' ability to predict and plan around timing. UMMS notes that the 120 day outside limit it recommends is well beyond the 30-day time period envisioned in the regulations governing the completeness review process, which provide for questions to be asked within ten days of filing, and a response ten days thereafter with up to one ten day extension.

UMMS further proposes to add a regulation confirming that a decision to dismiss a CON application for its failure to be complete is a final decision subject to reconsideration and judicial review procedures. Such finality is necessary to preserve an applicant's rights in the event that the dismissal for lack of completeness is due to a material dispute as to whether an applicant must provide requested information that is highly sensitive or otherwise burdensome and whether such information is required by the applicable review standards and criteria.

Consistent with these comments, UMMS proposes that the following changes to Regulation .08C.

The following language should added after Proposed Regulation .08C(3) and the subsequent subsections renumbered:

"(4) After staff has made a written request for additional information, any subsequent request for additional information made prior to docketing of the application shall be limited to information provided in response to staff's prior request, or requested but not provided."

The following language should added after Proposed Regulation .08C(5) and the subsequent subsections renumbered:

"(7) the Commission Staff shall docket or dismiss an application within 120 days of its filing, except as provided in Regulation .08A(2). The time period imposed by this subsection shall be stayed upon request of an applicant if a motion for protective order is pending.

(8) The dismissal of an application due to incompleteness shall be a final Commission decision for the purposes of reconsideration under Regulation .19 of this chapter and judicial review."[2]

4. Notice to the public, .08D(2)

Current procedural regulations require the Commission to publish notice of receipt of an application and of docketing. Proposed Regulation .08D adds a notice of publication for Letters of Intent not subject to a review cycle. UMMS agrees that in such circumstances, notice of receipt of the application is duplicative and not necessary. However, UMMS believes that for any project for which the letter of intent is not published in the Maryland Register, potential interested parties should receive publication notice of receipt of the application, to ensure sufficient time to plan a response and monitor and/or review any submissions. As a result, UMMS proposes the following changes to Proposed Regulation .08D(2):

"(2) Commission staff shall request that the *Maryland Register* publish notice to the public of its receipt of an application for which notice of receipt of a Letter of Intent was not published pursuant to Regulation .07A,and of the docketing of an application. The Commission shall also publish notice in a newspaper of general circulation in the area of the proposed project. Notices shall comply with the State Government Article §10-207, Annotated Code of Maryland, and shall include: ..."

5. Modifications to Letters of Intent and Applications, permitted modifications .08E

The Proposed Regulations should expressly retain the right in the existing regulation to modify a CON at any time to reduce capital costs, reduce beds or services, or respond to relevant changes in State Health Plan review standards. Such a right should exist in any review, including a comparative review (existing regulation limits this right to noncomparative reviews).

Also, the regulations should retain the existing express confirmation that changes to portions of a proposed project that refer to facilities and services not subject to CON review are not considered a modification.

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[2] UMMS numbers these subsection (7) and (8) rather than (6) and (7) due to the insertion of new subsection (4) also recommended in this comment.

UMMS proposes the following changes to Proposed Regulation .08E, and notes that the proposed additions are copied, verbatim, from existing regulation, except as noted regarding non-comparative reviews.

"(2) An application may be modified until the 45th day after docketing. After the 45th day of docketing, an application may only be modified as a result of a project status conference held pursuant to Regulation .09A(2) of this chapter or upon a showing of good cause. Modifications to an application to reduce capital or operating costs, reduce annual projected revenue, reduce the level or number of beds and services requested, or to respond to relevant changes in the State Health Plan review criteria, policies, or need projections, are permitted at any time.

(3) Changes to those portions of an application referring to facilities and services that are not subject to Certificate of Need review are not considered a modification to an application.

~~(3)~~(4) If an application is modified . . ."

6. Review Criterion .08G(3)(a), State Health Plan standards

Due to the many services within the Commission's regulatory authority and the continuously evolving landscape of health care services and reimbursement, there are times when metrics addressed in a State Health Plan chapter review standard are out of date and cannot or should not be met. UMMS suggests that the Commission formalize its authority to continue its current practice of permitting applicants to explain, in lieu of compliance, why a standard is out of date or inapplicable, and where appropriate, to suggest an alternative analysis that seeks to address the same issue or concern underlying the review standard. To achieve this, UMMS proposes the following addition to .08G(3)(a).

"An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards. An applicant asserting that a quality, performance, or safety metric addressed by a State Health Plan review standard is not applicable or

should not be applied because it is outdated, obsolete, or inaccurate, bears the burden of demonstrating why the standard should not apply. Where appropriate, the applicant may suggest alternative metrics that should be considered consistent with the policy or other considerations the standard in question addresses, and demonstrate that the applicant meets that metric."

7. Review Criterion .08G(3)(b) Need, and (c) Alternatives to the Project.

UMMS supports the proposed changes to review criteria .08G(3)(b), Need and .08G(3)(c), Alternatives to the Project, and believes these changes represent an appropriate focus for review based on the policies that these criteria seek to support.

8. Review Criterion .08G(3)(d), Project Financial Feasibility and Facility or Program Viability.

The Proposed Regulation removes the express consideration of "financial and nonfinancial" resources to implement the project, as well as the express inclusion of community support as a particular nonfinancial resource to be considered. While the proposed language leaves open (in its silence) the *possibility* that nonfinancial resources, including community support, may be considered, UMMS believes that potential parties and the Commission are better served by clarity on this issue. Community support has long been considered as a resource by the Commission, and UMMS recommends all nonfinancial resources, including community support, remain a consideration. In addition, nonfinancial resources are a particularly important consideration in circumstances where there may be a question as to whether an applicant for a new service or facility has the experience necessary to establish or sustain a project. For similar reasons, UMMS believes that nonfinancial resources should be a consideration not only to implement the project, but also to sustain it. Under the Proposed Regulation, as drafted, only revenue and demand are considerations to viability.

Finally, as a technical point, the consideration of viability for new services should also be applied where a CON is required for an expansion of an existing service.

"(d) Project Financial Feasibility and Facility or Program Viability. The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project and the

availability of financial and nonfinancial resources, including revenue sources and demand for the proposed services, adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced or expanded."

9. Review Criterion .08G(3)(e), Compliance with Terms and Conditions of Previous Certificates of Need.

Existing Regulation .08G(3)(e) requires an applicant to demonstrate compliance not just with terms and conditions of previous CONs, but also with commitments made that earned the applicant preference in a comparative review. In addition, existing Regulation .08G(e) permits an applicant to provide the Commission with notice and explanation as to why prior conditions or commitments were not met. UMMS recommends that both of these provisions be retained.

"(e) Compliance with all Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous CON granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met."

10. Review Criterion .08G(f), Project Impact.

The Proposed Regulation, as drafted, is confusing as to scope of costs and charges to be considered – as worded, it arguably considers costs and charges only of the proposed project. UMMS believes this criterion should continue to consider the impact on the cost and charges of other providers. As set forth below, UMMS proposes some punctuation and wording changes for clarity on this point.

In addition, the limitation of these considerations to the service area is misplaced because an applicant may define its service area unreasonably, either mistakenly or intentionally, exclude another provider's location, and thereby avoid an analysis of impact on that provider. UMMS recommends that the regulation expressly consider the impact on other providers in the Commission defined health planning regions included

within the applicant's defined service area.

UMMS further recommends that the regulation expressly provide the Commission authority to consider impact in making its decision. As worded, the existing regulation and the Proposed Regulation require only "documentation" by the applicant, but do not give the Commission express authority to consider impact in rendering its decision. The degree to which adverse impact is material to the Commission's decision varies service by service. As a result, UMMS does not propose to define the degree of impact that may result in a denial, other than to define a threshold of material adverse impact.

"(f) Project Impact. An applicant shall provide information and analysis with respect to the impact of the proposed project on the costs and charges of the applicant and other providers for the facilities and services included in the project, and on access to those facilities and services, in any health planning region included within the proposed ~~the~~ service area of the project. The Commission may, but need not, deny a project, or any portion thereof, that is substantially likely to cause another service or facility to be materially adversely affected, as that term is defined in Regulation .01B(2)."

H. Regulation .09, Commission Decision and Action on CON Applications

1. Regulation .09A(1)(a), Preparation of Proposed Decision

UMMS proposes the following modification to Proposed Regulation .09A(1)(a) for clarity:

"(a) In a noncomparative review in which no interested party has submitted written comments opposing an application, or in a noncomparative or uncontested review in which no evidentiary hearing is held in accordance with Regulation .11 of this chapter, Commission staff shall review the application and prepare a staff report and recommendation for consideration by the full Commission."

2. Regulation .09B, Exceptions – interested parties

UMMS is concerned with a process whereby persons may be granted "interested party" status under Regulation .08F and are permitted to file exceptions opposing recommended approval of a project despite not having filed initial comments stating with "particularity the State Health Plan standards or the review criteria" that the person seeking interested party status believes have not been met by the applicant and the reasons why the applicant does not meet those standards or criteria. Such a process permits an "interested party" to effectively "lie in wait" and file written exceptions after the review process has been completed. Aside from being unfair to the applicant, this adds significant cost, time, and effort to the review process for applicant, Commission Staff, and any appointed Reviewer. UMMS therefore proposes that Regulation .09B(1) be amended to require that an interested party filing exceptions opposing a recommended CON approval must have previously filed comments opposing the project in accordance with Regulation .08F(1)(c)-(d).

> "(1) Pursuant to State Government Article §10-216, Annotated Code of Maryland, each applicant and interested party who has submitted comments under Regulation .08F(1) of this chapter may submit written exceptions to a staff report and recommendation or a proposed decision and make oral argument to the Commission. <u>An interested party filing exceptions opposing a recommended project approval shall have previously filed written comments in accordance with Regulation .08F(1)(c)-(d).</u>"

3. Regulation .09B, Exceptions – timing and page limits

UMMS is also concerned with the proposed removal of a minimum time period for issuance of a schedule for the submission of exceptions and the new imposition of page limits on exceptions. Recommended decisions can, at times, be the culmination of years of planning, hundreds of thousands of dollars invested in planning a multi-million dollar project, and a multi-year review process. The written decisions themselves can reach from close to a hundred pages to many more, especially in contested and comparative reviews. Written exceptions are a party's sole opportunity to put forth written advocacy to the full Commission and, as provided in both existing and Proposed Regulation, a party must "specifically identify each finding and conclusion" to which the party takes exception. These exceptions have a material impact on a party's right to appeal, as the party will be limited to issues raised in its exceptions. A twenty-five page

limit is insufficient in light of the significant scope of some reviews. Similarly, a time period less than what the existing regulations provide as a very rushed minimum (7 days for exceptions, 5 days for a response) is insufficient for a party to review, digest, and raise exceptions and responses to a recommended decision of significant length and substance. This is especially true when, as is sometimes the case, parties are not aware that a recommended decision or staff report will issue in advance of a particular Commission meeting, and are not able to clear the schedules of those involved in the review without such notice.

As a result, UMMS proposes that Proposed Regulation .09B(2)-(3) be revised to increase, not remove, the existing minimum time periods, and to remove the addition of page limits consistent with existing regulation. In the alternative to increasing the minimum time periods (which are much shorter than any Maryland court rules), UMMS would support regulation that keeps the existing minimums but includes a provision that staff or a reviewer would provide at least seven days' notice that a report or decision will issue, so that parties may plan appropriately.

"(2) Schedule.

(a) Upon issuance of a staff report or proposed decision, Commission staff shall issue a notice specifying the schedule for the submission of exceptions and any response, the date on which the Commission shall hear oral argument, and rules for conduct of the hearing.

(b) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff shall specify that a party filing exceptions has at least ten days to file exceptions, and a party filing a response to exceptions has at least 7 days to file a response. The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.

~~(2)~~ (3) Exceptions shall specifically identify each finding and conclusion to which exception is taken, citing those portions of the record on which each exception is based.

~~(a) Exceptions shall be limited to 25 pages, double-spaced, excluding attachments.~~

~~(b) Responses to exceptions shall be limited to 15 pages, double-spaced, excluding attachments.~~"

4. Regulation .09B, Exceptions - Participating Entities

UMMS proposes to retain the existing requirement that a participating entity may not request the opportunity to address the Commission before Commission action on an application unless that participating entity has timely filed comments on the applicant's compliance with the State Health Plan standards and review criteria. The Commission has on occasion liberally granted participating entity status to participants that make general public interest comments or otherwise wish to remain apprised of a review but who do not submit comments that address the applicant's conformity with standards and criteria. UMMS understands the Commission's desire to liberally include community voices, but does not believe that such parties should be permitted the opportunity to present oral argument. By necessity, participating entities whose comments did not address review standards and criteria will either not be presenting oral argument on an issue properly before the Commission, or if they do, they will be presenting comments to which an applicant was not given appropriate notice and due process to consider and oppose.

UMMS further proposes to provide additional notice to parties that a participating entity will present oral argument, so that parties may have sufficient time to prepare.

UMMS proposes to modify Proposed Regulation .09C(1)(a) as follows.

"(1) Request by Participating Entity to Address the Commission.

(a) <u>In a project upon which it timely filed comments on an applicant's conformance with State Health Plan standards and review criteria, and a</u>~~A~~fter the issuance of a staff report or a reviewer's proposed decision, a participating entity may request the opportunity to address the Commission before Commission action on the application, by submitting a written request at least ~~three~~ <u>seven</u> days before the scheduled Commission meeting.

(b) The Chair of the Commission, after consultation with the Executive Director, may permit a participating entity, or combination of participating entities, who submit(s) a request in conformance with subsection (1)(a), to make an oral presentation to the Commission on matters it addressed in written comments on the application.

(c) At least ~~one~~ five days before the scheduled Commission meeting that will consider an application, the Executive Director shall advise each applicant, interested party, and participating entity in a review whether the Chair will permit a participating entity or combination of participating entities to make an oral presentation to the Commission, and shall specify the format of the presentation."

5. Regulation .09E, Action on the Application

Proposed Regulation .09E(3) proposes to add a stay provision to a CON review. This may thwart the intent of MARYLAND CODE, HEALTH-GENERAL § 19-126 (i), *i.e.*, the requirement that the Commission act and not unnecessarily delay reviews. UMMS proposes that the Proposed Regulation permitting a stay define who may initiate the request for a stay, provide the opportunity for parties and interested parties to respond before a stay is granted, and provide that the stay may not be for more than three months if not consented to by all parties and any party with a pending application that cannot be docketed until the review of the application that is the subject of the stay is complete.

"(3) On motion by a party or interested party consistent with regulation .10C, or by request of Commission Staff or a reviewer and with the opportunity for any party or interested party to respond, a~~A~~ review of a CON application may be stayed ~~for a period not to exceed six months~~ if the reviewer, or if a reviewer initiates the request for stay or is not appointed, the Executive Director, determines that there is good cause for a stay. A stay opposed by a party, interested party, or party with a

pending application that cannot be docketed until the review is complete, may not exceed three months. A consent stay may not exceed six months."

6. Regulation .09E, Action on the Application

The removal of language requiring Commission Staff to report on the status of CONs in which a staff report is not issued within 90 days is inappropriate and unwarranted. The commissioners and the public should be apprised of any reviews experiencing a significant delay. This requirement is more important than ever, given the recent statutory changes and proposed regulatory changes regarding deemed approval of certain CONs if not acted on within a certain time period. The Commission and public should be made aware of when a CON review is approaching the deadline on which it may be deemed approved without any decision by the full Commission. UMMS proposes to revise Proposed Regulation E(1) to add, verbatim, the existing regulatory text governing this issue.

"E. Action on the Application.

The Commission shall act on an application for a CON not later than 150 days after the application has been docketed. If no evidentiary hearing is held, the Commission shall act on an application within 90 days after the docketing of the application. Staff shall report to the Commission the status of all projects where a staff report is not issued for Commission action within 90 days."

I. Regulation .10, Miscellaneous Rules and Procedures

1. Time Frames for Responses to Motions

The Commission proposes to limit the timeframe for applicants or interested parties to respond to motions to five days, pursuant to Proposed Regulation .10C(5). Currently, the procedural regulations permit parties to file one written answer to a motion in the same format as a motion, but the rules do not specify any time frame in which such answers must be filed. The Commission also proposes to retain the ten-day time frame for applicants to respond to a Commission staff's motion for summary decision to deny the application. To enable parties to meaningfully respond to motions, UMMS proposes

to extend the time frame for responses to motions and to motions for summary decision to fifteen days, in accordance with the time frame to file interested party comments.

UMMS proposes the following changes to Proposed Regulation .10C(5):

> "(5) An applicant or interested party to the review may file one written answer to a motion, in the same format required of motions, within ~~five~~ fifteen days of the filing of the motion."

UMMS proposes the following changes to Proposed Regulation .10D(2):

> "(2) The motion shall identify the grounds for the motion, which is not required to address every applicable State Health Plan standard. The applicant may respond to the motion in writing, within ~~ten~~ fifteen days of receipt of the motion."

2. Proposed Regulation .10J, Certificate of Need or other Commission approval is not transferable

UMMS recommends that the Commission add clarifying language to Proposed Regulation 10.24.01.10J to confirm the Commission's position and the Court's holding in *Carriage Hill Cabin John, Inc. v. Maryland Health Care Commission*, 125 Md.App. 183 (1999). This regulation has been interpreted in various ways over the years. It would be appropriate and helpful to confirm that the non-transferability of a Commission approval does not "prohibit corporate affiliation or acquisition per se, because that would render the CON process too inflexible in the current health care business climate." *Id*., 125 Md.App. at 257 (internal quotation marks and brackets omitted). UMMS further recommends that the Commission add language expressly recognizing that a person with a pending application or request may similarly proceed with an affiliation or acquisition without jeopardizing the pending application or request.

> "J. Certificate of Need or other Commission approval is not transferable.
>
> (1) A corporate affiliation, acquisition, or other reorganization affecting the corporate structure or upstream ownership of the owner or licensee of a CON or other Commission approval shall not be deemed a transfer if there is sufficient identity between the persons or entities responsible for the

development and operation of the facility or service before and after the transaction such that the Commission had sufficient information to evaluate compliance with applicable review standards and criteria at the time that it rendered its decision.

(2) A change in corporate affiliation, acquisition, or other reorganization affecting the corporate structure or upstream ownership of a person or entity with a pending CON application or other pending request shall not be deemed a modification or a violation of these Regulations if the change would not be deemed a transfer of CON or other approval under regulation .10J(1) were the pending application or request approved at the time of the change."

3. Consent Agenda Process – Regulation .10K(2)

The Commission Staff proposes to add a consent agenda process for its meetings at Regulation .10K. UMMS supports the addition of this process, which should allow the Commission to streamline its meetings and focus discussion on substantive or disputed issues. The proposed consent agenda process at Proposed Regulation .10K(2) states "[a]n item on the consent agenda shall be moved to the main agenda of the upcoming meeting or the meeting that follows if a commissioner requests that the item be moved to the main agenda." As currently drafted, this process is not clear about whether consent agenda items will be removed to the main agenda in advance of the meeting or during the meeting, and thus, whether it permits a commissioner to ostensibly delay consideration of an issue for an entire month or more until the next Commission meeting. Just because an issue is worthy of discussion or deliberation does not necessarily warrant a delay in voting on it for an entire month, which could adversely affect the party whose project is under review. UMMS proposes the current process outlined at Regulation .10K(2) be replaced in its entirety with the following process:

"(2) Consent agenda items will be disseminated to the Commissioners prior to the meeting along with copies of any related materials. At the beginning of the meeting, the Chair of the Commission will present the consent agenda to the Commissioners

and ask whether anyone wishes to remove an item from the consent agenda to the main agenda. Items may be removed from the consent agenda on the request of any one Commissioner. Items not removed may be adopted by general consent without debate. Removed items may be taken up either immediately after the consent agenda or placed later on the agenda at the discretion of the Chair."

J. Regulation .11, Evidentiary Hearings

1. Request for Evidentiary Hearing – Regulation .11A

The Proposed Regulations retain the right of an applicant or interested party to request an evidentiary hearing in a CON review of a health care facility other than an ambulatory surgical facility, but arguably remove the right to make such a request in a review concerning the addition of services. UMMS believes that requests for some new services should be scrutinized to the same degree as requests for new facilities and does not believe this distinction provides a reasonable basis for a difference in the right to request a hearing. For example, cardiac surgery and organ transplant services are significant services that merit considerable scrutiny. The Proposed Regulation, as drafted, would afford fewer rights to an applicant for such services than to an applicant for a hospice or home health care agency.

The Proposed Regulations remove the rights of parties to request oral argument on the question of whether to conduct an evidentiary hearing, and removes the right to appeal an adverse ruling on this question by motion to the full Commission. These changes concern UMMS because they restrict a party's current procedural rights, which have already been significantly reduced from prior, more robust procedures for evidentiary hearings that existed prior to the current regulations. Consistent with General Comment I.E, UMMS believes that the Commission should continue to permit oral argument in all instances where permitted by the regulations currently in effect. UMMS is also concerned that a reviewer rarely issues a decision as to whether to hold an evidentiary decision at a meaningful time in a review, often issuing the ruling shortly before issuing a recommended decision. This deprives the parties of a meaningful opportunity to use the currently existing appeal procedure while the matter is still under active consideration. UMMS therefore recommends that the regulations maintain the current right to oral argument and to appeal a decision, and further recommends that the regulations be modified to impose a new time period on when a ruling will be made.

"A. Request for Evidentiary Hearing.

(1) Except as otherwise provided in these regulations, a request for an evidentiary hearing shall be made within 45 days of the docketing of an application or within 30 days after the modification of an application in a review.

(2) At the request of an applicant or interested party, the Commission may hold an evidentiary hearing in the review of a CON application for the addition of a new service or services or for any health care facility other than an ambulatory surgical facility, if, in the judgment of the reviewer, an evidentiary hearing is appropriate due to the magnitude of the impact that the proposed project may have on the health care delivery system and the project, if approved, would result in one of the following:

[list of items (a)-(d) in Proposed Regulations omitted here for brevity;]

…

(3) A reviewer shall rule on a request for an evidentiary hearing within 60 days of the request, or within 60 days of being appointed as reviewer, whichever is later. The reviewer may hear oral arguments from any party on the question of whether to conduct an evidentiary hearing.

(4) A party or interested party may appeal an adverse ruling on a request to conduct an evidentiary hearing by motion to the full Commission at its next regular meeting."

2. Conduct of Evidentiary Hearings – Regulation .11B(2)

The proposed changes to the procedure governing judicial notice during an evidentiary hearing remove a significant procedural right of a party to demonstrate that a fact on which a reviewer may take notice is incorrect or inapplicable. This is an important procedural safeguard and should not be removed. UMMS therefore suggests adding

language to Proposed Regulation .11B(2)(g) that exists in its corollary, existing Regulation .11A(3)(g), but is stricken from the Proposed Regulations, except that UMMS has revised the word "Commission" to "reviewer" in two instances.

> "(g) The reviewer may take administrative notice of all judicially cognizable facts to the same extent as courts of this State, either on the reviewer's own motion or at the request of a party. The reviewer may also take official notice, without meeting formal evidentiary rules, of general technical or scientific facts within the specialized knowledge of a member of the Commission. A party to the hearing is entitled, on timely request, to an opportunity to show that the reviewer should not take administrative or official notice of specific facts and matters, or that the fact or matter to be officially noticed is inapplicable to the proceeding or is incorrect or misunderstood by the reviewer."

3. Prehearing Procedures – Regulation .11C

UMMS believes that the prehearing conference procedure as it currently exists is necessary as it allows both the parties and the reviewer predictability as to how an evidentiary hearing will be conducted. The absence of a defined prehearing conference procedure prior to an evidentiary hearing would require parties to invest considerable time and resources into preparations that they could readily determine are unnecessary at a prehearing conference. The existing regulation notes that the purpose of the prehearing conference is to "expedite the evidentiary hearing." That is an appropriate goal and should be maintained by maintaining the existing regulation as a procedural safeguard. UMMS proposes that the regulation governing prehearing procedure remain unchanged, and that the Proposed Regulations be modified as followed. The proposed changes below are copied, verbatim, from existing Regulation .11B.

> "C. Prehearing Procedures.
>
> (1) The reviewer ~~may~~ shall hold a prehearing conference, as well as settlement conferences before an evidentiary hearing.

(2) The reviewer shall notify each applicant and interested party of the prehearing conference in writing. The notification shall:

(a) Include the date, time, and place of the prehearing conference or conferences;

(b) Summarize the rules of procedure governing the evidentiary hearing; and

(c) State the dates, if known, for the submission of prefiled testimony and the date, time, and place of the evidentiary hearing.

(3) The principal purpose of the prehearing conference is to expedite the evidentiary hearing. To this end the reviewer may, among other things:

(a) Instruct the parties to:

(i) Formulate and submit a list of genuine contested issues to be decided at the hearing;

(ii) Identify each potential witness, the subject matter of each witness's testimony, and documents to be introduced; and

(iii) Raise and address issues that can be decided before the hearing;

(b) Encourage stipulations as to facts, law, and other matters;

(c) Schedule dates for the submission of prefiled testimony, further prehearings, the hearing, and submission of briefs and documents; and

(d) Rule on any pending motions.

(4) A written summary of the prehearing conference shall be made a part of the record of the proceeding.

(5) The reviewer may record the prehearing conference or have a stenographer present.

~~(2)~~ (6) A request for the postponement of a hearing shall be made at a reasonable time before the hearing and is granted only for good cause shown, at the discretion of the reviewer."

4. List of Genuine Issues – Regulation .11D

Proposed Regulation .11D significantly modifies existing Regulation .11C by divorcing the genuine issues that may be considered at an evidentiary hearing from any regulatory requirement at issue in the review. This significantly broadens the potential scope of review, and the potential burden on parties and interested parties to prepare and present evidence on issues that extend outside of the Commission's purview. Evidentiary proceedings should be expressly limited to issues material to the regulatory review standards and criteria at issue in an application so that a party may have appropriate procedural safeguards in place to protect it from a burdensome inquiry into matters outside this Commission's scope of authority in an evidentiary hearing on a CON matter. As a result, UMMS proposes that Proposed Regulation .11D be modified to add language that currently exist, verbatim, in its corollary existing regulation, .11C(2):

"D. List of Genuine Issues.

(1) The reviewer shall establish a list of genuine issues of material fact for the evidentiary hearing.

(2) An evidentiary hearing may be held only on those genuine factual issues ~~or issues on~~ for which

(a) There is a significant dispute as to factual issues; and

(b) One of the following is true:

(i) The reviewer designates a genuine issue;

(ii) An applicant or an interested party has made a prima facie case that a particular standard or criteria has not been met by an applicant;

(iii) An applicant has made a prima facie case that it deserves preference over another applicant under that standard or criteria; or

(iv) The reviewer determines that testimony on an issue would be useful in rendering a decision."

K. Regulation .12, Post-Approval Obligations

UMMS is supportive of many of the modifications to Proposed Regulation .12 for CON holders, including the change from strict performance requirements to allowing an applicant to define its own project implementation schedule in Proposed Regulation .12A and the change from quarterly to semi-annual progress reports in Proposed Regulation .12B.

As reflected in the suggested change to the definition of "holder" above, UMMS believes that Proposed Regulation .12A and .12E-G should provide the Commission with adequate oversight as to the implementation of a project excepted from CON review under Proposed Regulation .03 or exempted from CON review under Proposed Regulation .04. Applicants obtaining Commission approval for projects excepted or exempted from CON review should not be required to submit progress reports under Proposed Regulation .12B or obligate capital within the time frames specified by Proposed Regulation .12C.

1. Project Implementation Schedule – Regulation .12A

Given UMMS' proposed definition of "holder," UMMS proposes the following change to Regulation .12A(3) to ensure that projects not subject to CON review be governed by the project implementation schedule submitted in an application for Commission approval:

"(3) A holder or a person receiving other Commission approval for a project must abide by the project implementation schedule submitted with its application for a CON or other Commission Approval."

2. Grounds for Withdrawal of Commission Approval – Regulations .12E

Given UMMS' proposed definition of "holder," UMMS proposes the following amendments to ensure that projects not subject to CON review be governed by Proposed Regulation .12E:

"E. Grounds for Withdrawal of Commission Approval. The Commission may withdraw a CON or other Commission approval if it finds that:

(1) The holder or a person receiving other Commission approval for a project made a material misrepresentation upon which the Commission relied in approving the application;

(2) The holder or a person receiving other Commission approval for a project failed to demonstrate sufficient progress in implementing the project;

(3) The holder or a person receiving other Commission approval for a project has failed to obligate or complete an approved project as required by §A of this regulations;

(4) The holder or a person receiving other Commission approval for a project failed to meet a condition in the approval;

(5) The holder or a person receiving other Commission approval for a project failed to timely provide the annual progress report required under §A of this regulation; or

(6) The project differs materially from that approved by the Commission."

3. Withdrawal of CON or Other Commission Approval – Regulation .12F

Proposed Regulation .12F(3) should be amended to provide flexibility in maintaining a CON or other determination issued by the Commission. Further, given UMMS' suggested definition of holder Proposed Regulation .12F should be revised as follows:

"F. Notice Before Withdrawal of a CON or Other Commission Approval.

(1) If Commission staff determines that a CON or other Commission approval should be withdrawn, Commission staff shall inform the holder or a person receiving other Commission approval for a project and each appropriate local health department, setting forth in writing the reasons for the proposed withdrawal.

(2) This notice shall set forth the right of the holder or a person receiving other Commission approval for a project to submit written argument in support of its position and present oral argument to the Commission, as well as the right to an evidentiary hearing conducted in accordance with Regulation .11 of this chapter, to show cause why the approval should not be withdrawn.

(3) A holder or a person receiving other Commission approval for a project that has failed to demonstrate sufficient progress in project implementation must show that the lack of progress resulted from factors beyond the holder's control or for good cause shown."

4. Final Action – Regulation .12G

Given UMMS' suggested definition of "holder," Proposed Regulation .12G(3) should be amended as follows:

"(3) Be transmitted to the holder or a person receiving other Commission approval for a project and to each appropriate local health department within 30 days of the date of action by the Commission."

5. Regulation .12H

Given UMMS' suggested definition of "holder," Proposed Regulation .12H should be amended as follows:

"~~F~~H. CON Application after Withdrawal of a Prior CON. If a CON or other approval is withdrawn due to lack of sufficient progress in implementing the project, the holder or a person receiving other Commission approval for a project may file an application seeking Commission approval to initiate or complete the previously authorized project, which shall be considered a new application by the Commission."

L. Regulation .13, Certificate of Conformance and Ongoing Performance

1. Completeness – Regulation .13C

Under Proposed Regulation .13C(2), the Commission Staff would have authority to request information to make the application complete, as well as to "request additional information beyond that required to make the application complete." As discussed in Section II.G.3 above, UMMS has concerns about the length and scope of completeness review. One driving force behind the issuance of these revised procedural regulations is the desire to reduce the costs associated with reviews and shorten the time involved in reviewing a proposed project. UMMS has received burdensome requests for information in past reviews where the information sought was not material to the determination of whether UMMS had met the applicable criteria or review standard(s). UMMS proposes a procedural change that would require all requests for additional information to be asked in a single written request, except where Staff responds to or seeks additional information regarding information provided by the applicant in response to the first request. UMMS anticipates such a change would reduce the burdens, cost, and time associated with responding to requests for information that are not material to the Commission's review, while allowing Staff to obtain all information necessary to render a decision. UMMS proposes to amend Proposed Regulation .13C(2) as follows:

"(2) Staff's written request for information to make the application complete shall specify the necessary information. Staff may request additional information beyond that required to make the application complete provided such additional information is material to the determination of whether the applicant has satisfied the criteria and standards for approval. The applicant shall provide the completeness and additional information within 15 business days unless an extension is requested and granted."

UMMS further proposes that the following language should be added after Proposed Regulation .13C(2) and the subsequent subsections renumbered:

"(3) After Staff has made a written request for information to make the application complete, any subsequent request for additional information during completeness shall be limited to information provided in response to Staff's prior request, or requested but not provided."

2. Additional Information – Regulation .13D

The Commission Staff proposes to give staff the ability to request information from an applicant supplementing an application at any time during the review of an application and to set the applicable time limit in which the applicant must respond to such requests in Proposed Regulation .13D (1) and (2). In accordance with Sections II.G.3 and II.I.1 above, UMMS proposes to clarify the language in these proposed sections to make clear that any additional information requested must be material to the determination of whether the applicant has satisfied the criteria and standards for approval. This proposed change will facilitate more efficient reviews of certificates of conformance and ongoing performance and reduce the cost associated with such reviews. UMMS proposes the following changes to regulation .13D:

"D. Additional information. Commission staff may:

(1) Request information from an applicant supplementing an application at any time during the review provided that such additional information is material to the

determination of whether the applicant has satisfied the criteria and standards for approval; and

(2) Set reasonable time limits for the applicant to supply the requested information, which may be extended upon request by an applicant for good cause."

3. Time to Act on a Certificate of Conformance – Regulation .13F

Proposed Regulation .13F states that the Commission shall act on an application for a certificate of conformance not later than 150 days after the staff determines that the application is complete. To align with MARYLAND CODE, HEALTH-GENERAL § 19-126(i), which provides the Commission with 120 days to act on an uncontested CON, UMMS proposes that the Commission shorten the time frame in which it must act on an application for a certificate of conformance in Regulation .13F from 150 days to 120 days. The efforts involved in the Commission's review of a certificate of conformance should be in line with, or may even be less burdensome, than the review of an uncontested CON. As a result, 120 days should be sufficient time for the Commission to take action on a certificate of conformance. UMMS proposes the following revised language:

"The Commission shall act on an application for a certificate of conformance not later than ~~150~~ 120 days after staff determines that the application is complete."

4. Exceptions – Regulation .13I

Proposed Regulation .13I(2) provides that the when the Commission issues a staff report and recommendation pursuant to Regulation .13, such report and recommendation shall be accompanied by a schedule for submitting exceptions and the date of the Commission meeting at which the Commission shall hear oral argument on any exceptions. As discussed in more detail in Section II.H.3 above, UMMS suggests that the Commission set forth a minimum time frame in which parties will have the opportunity to file exceptions to a staff report and recommendation on applications for Certificates of Conformance and Certificates of Ongoing Performance. UMMS proposes to amend Proposed Regulation .13I as follows:

"I. Exceptions.

(1) An applicant may submit exceptions to a staff report and recommendation and present oral argument on its exceptions to the Commission.

(2) Staff's issuance of a staff report and recommendation shall be accompanied by a notice that specifies the schedule for the submission of exceptions and the date of the Commission meeting at which the Commission shall hear oral argument on exceptions. Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff shall specify that a party filing exceptions has at least ten days to file exceptions, and a party filing a response to exceptions has at least 7 days to file a response. The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.

(3) Exceptions shall specifically identify each staff conclusion to which exception is taken, citing those portions of the record on which each exception is based.

~~(4) Exceptions and any response to exceptions shall be limited to 25 pages, double- spaced, excluding attachments.~~

(4) ~~(5)~~ Commission staff may file a written response to exceptions and present oral argument at the exceptions hearing.

(5) ~~(6)~~ Oral arguments on exceptions to the staff report and recommendation and any response shall be limited to ten minutes per argument unless extended by the Chair of the Commission."

6. Approval of Applications with Conditions - .13J

Proposed Regulation .13 implements MARYLAND CODE HEALTH-GENERAL § 19-120.1. In the statute, the legislature directed the Commission to issue regulations that "require, as a condition of the issuance of a certificate of conformance or a certificate of ongoing performance, that an acute general hospital agree to voluntarily relinquish its authority to provide cardiac surgery services, emergency PCI services, or elective PCI services if the hospital fails to meet the applicable standards established by the Commission." HEALTH-GEN. § 19-120.1(g)(2)(v). Aside from this specific condition

regarding relinquishment of authority to provide services, the statute does not grant the Commission any authority to impose additional conditions upon a certificate of conformance. Proposed Regulation .13, however, would grant the Commission the ability to approve an application for a certificate of conformance with conditions. Proposed Regulation .13 as currently drafted exceeds the statutory authority granted to the Commission pursuant to HEALTH-GEN. § 19-120.1, and must therefore be revised. UMMS proposes the following edits to .13J(1):

"J. Final Decision on an Application for Certificate of Conformance.

(1) A final decision on an application for a certificate of conformance shall contain findings of fact and conclusions of law and shall:

(a) Approve the application;

~~(b) Approve the application with conditions;~~ or

(b) ~~(c)~~ Deny the application."

M. Regulation .14, Special Procedures

1. Determination of Coverage -- .14(A)

Proposed Regulation .14A(2) requires the Executive Director of the Commission to act on a determination of coverage request within 30 business days of receipt of complete information. In accordance with UMMS' comment under Section I.B above and in line with the Commission's addition of deemed approvals for notices of acquisition of health care facilities under Proposed Regulation .03A(2), UMMS Proposes a new section .14A(7) providing for deemed approvals of determination of coverage requests that otherwise comply with the procedural requirements of Proposed Regulation .14A, as follows:

"(7) If the Commission fails to issue a determination in accordance with section §(6) within 30 days receipt, a request submitted in accordance with §(A) shall be deemed approved."

2. Determination of Coverage Conditions -- .14(6)

A determination of coverage is a determination by the Commission as to whether CON review is or is not required for a particular project. Accordingly, the Commission

should not be permitted to impose conditions on a determination. UMMS suggests that Proposed Regulation .14(A)(6) be amended as follows:

"(6) The Executive Director may issue a determination that:

(a) Certificate of Need or other Commission review is not required~~,~~ ~~with or without conditions~~; or

(b) Certificate of Need review is required for stated reasons."

N. Regulation .17, Project Changes After Commission Approval

1. Project Changes After CON Approval - .17(A).

In prior contested reviews, the Commission has approved CONs subject to conditions, which the CON holder subsequently seeks to have removed through post-approval project changes. Other times, a CON holder has made changes that while permissible under Proposed Regulation .17B, result in significant and material changes to the approved project. In such cases, interested parties and participating entities should be permitted to participate in the Commission's review of post-approval project changes.

Accordingly, the CON holder or the Commission Staff should notify all interested parties and participating entities of all post-approval CON modification requests. Section .17(A) should be amended to state:

"A. A holder that desires to change a project that has received a CON ~~or other Commission approval~~ shall submit a request for the proposed change and supporting documentation to the Commission, copying each local health department within the health planning region of the project, each interested party and participating entity involved in the CON Review, and, in the case of a change in the location or address of a project involving construction of a new health care facility, to all health care facilities of that type located in the health planning region. Interested parties and participating entities involved in the CON Review may submit comments on the holder's project changes in accordance with the

procedures and standards set forth at Regulation .08F(1) and .08F(2). Holders that desire to change a project may respond to comments submitted by interested parties and participating entities in accordance with the procedures and standards set forth at Regulation .08F(3)."

2. Inflation Allowance Index – Regulation .17B(2)

To determine the inflation allowance of an approved capital budget and whether a post-approval project change for capital costs exceeding the approved capital budget is required, existing Regulation .17B(2) requires application "Building Cost Index published in the Health Care Cost Review." Proposed Regulation .17B modifies the inflation index reference to require application of "the Hospital Capital Market Baskets published by IHS Markit in Health Care Cost Review or other guidance approved by the Commission and posted on the Commission website."

The inflation index selected by the Commission must be readily available and up-to-date, especially given the significant changes in inflation in recent years and how much this can impact a project's inflation allowance. This is not the case for The IHS Markit Index referenced in the Proposed Regulations, which is not updated regularly on the Commission's website and the guide itself is not readily available to the industry. For example, the IHS Markit Index information on the Commission's website was last updated on March 3, 2021 and only projects inflation through the third quarter of 2023. In contrast, CON applicants are already required to have access to the Marshall & Swift Valuation Service ("MVS") Guide, which incorporates inflation, in order to perform the MVS analysis required by many State Health Plan chapters. The MVS Guide is updated monthly, which is more frequently than the IHS Markit Index, and provides local update factors that may be able to more accurately capture local or regional inflation factors than the IHS Markit Index which is a national index. Accordingly, UMMS proposes that the Commission permit CON holders more flexibility to select between the IHS Markit Index, other guidance posted by the Commission on its website, and the MVS Guide when applying inflation for purposes of Regulation .17B(2), as follows:

"(2) A capital cost increase that exceeds the approved capital cost inflated by an amount determined by applying the Hospital Capital Market Baskets published by IHS Markit in Health Care Cost Review, ~~or~~ other guidance approved by the Commission and posted on the Commission website, or the Marshall & Swift

Valuation Guide Index from the application submission date to the date of the filing of a request for a project change;"

3. Review Criteria and Interested Party and Participating Entity Comments to Project Changes – Regulation .17D(1)

Neither the current regulations nor the Proposed Regulations include review criteria for the Commission in considering modifications to approved CONs. UMMS suggests that Proposed Regulation .17D(1) be amended to expressly incorporate the review criteria set forth in Proposed Regulation .08G as follows:

"(1) Requested changes subject to review under §B of this regulation shall be reviewed by the Commission in accordance with the review criteria set forth in Regulation .08G."

4. Deemed Approval of Project Change Requests – Regulation .17D(3)

Regulation .017D(3) provides that for project changes subject to Commission review under Section B of this regulation, "[t]he Commission shall provide a written notification within 45 days of the Commission's receipt of a complete change request that: (a) The proposed change is approved in whole or part and incorporated into a modified CON or other modified approval for the project with conditions as appropriate; or (b) The proposed change is denied, with explanation." For the same reasons as discussed in Section I.B above, UMMS proposes that a new section .17D(4) be added to provide for a deemed approval if the Commission does not provide a final decision on the project change within the 45 day prescribed time frame, as follows:

"(1) A project change request submitted in accordance with §A that is subject to Commission review under §B and is not an impermissible change under §C shall be deemed approved if final action by the Commission does not occur within 60 days after the Commission receives a project change request and provides all information requested by Commission Staff."

O. Regulation .18, Review Required before Licensing and First Use

Given UMMS' proposed definition of "holder," UMMS proposes the following amendments to ensure that projects not subject to CON review be governed by Proposed

Regulation .18A. Further, Proposed Regulation .18A should be amended to reflect actual construction projects. Documentation of final construction costs cannot be provided before a project is completed. Finally, Proposed Regulation .18A(2) should incorporate any project changes approved under regulation .17.

UMMS suggests that .18A be amended to state as follows:

"A. Request for First Use Review and Approval. Not fewer than 60 days but not more than 120 days before the first use of any portion of a facility or service developed under a CON or other Commission approval, the holder or person receiving other Commission approval for a project shall specify the anticipated date for first use and request in writing, through the Center for Health Care Facilities Planning and Development, a final review and first use approval. The request shall include:

(1) Documentation of the final estimated cost of the project[.]"

(2) A description of any differences in physical plant design, space, or services in the finished project when compared with the description of the project reviewed and approved by the Commission in the original CON approval or through a post-approval project change approved under Regulation .17."

P. Regulation .19, Reconsideration Procedures

Consistent with Comment I.E above, UMMS believes that the Commission should continue to permit oral argument in all instances where permitted by the regulations currently in effect. UMMS therefore suggests adding language that exists verbatim in the current regulations but is stricken from the Proposed Regulations. For organization purposes, UMMS proposes relocating the language from .19C, where it currently appears, to .19A, by modifying Proposed Regulation .19A as follows:

"A. Request for Reconsideration. For good cause shown, an aggrieved party may request that the Commission conduct a hearing to reconsider a Commission final decision to grant, to grant with conditions, or to deny a Certificate of Need

application, a request for an exemption from CON review, or other Commission approval issued under this chapter. This request shall be in writing and filed with the Center for Health Care Facilities Planning and Development within 15 days of the date upon which the Commission renders its decision. A request to present oral arguments shall be made at the time of filing an initial request for reconsideration or a response."

Q. Regulation .20, Emergency Certificate of Need

Proposed Regulation .20 governs the award of an emergency CON. Until the COVID-19 pandemic, this rule was rarely used. During the pandemic, the Commission granted many emergency CONs, principally to increase the inpatient capacity at numerous Maryland hospitals. The proposed amendments would expressly permit the Commission to award an emergency CON to address a public health emergency. The amendments also set forth a streamlined process that largely follows the procedures that the Commission used when it authorized emergency expansion of hospital capacity during the pandemic. UMMS supports the proposed amendments to this rule, but requests one clarifying modification. In subsection E, language should be added to state that the duration of an emergency CON shall be extended automatically during any period of time when the applicant has properly and timely sought a CON to retain the capacity or project approved on an emergency basis.

Also, to preserve procedural rights, UMMS proposes to allow an emergency CON applicant to seek consideration by the commissioners if the Commission Staff determines to deny an emergency CON. UMMS proposes the following additional language in Proposed Regulation .20:

"F. Action on a Denied Application. In the event the Executive Director denies a request for an emergency CON, the applicant may seek reconsideration of the denial from the full Commission at the next public meeting of the Commission. The decision of the full Commission shall be a final order for purposes of judicial review."

R. Regulation .22, Effective Date

UMMS proposes to modify Proposed Regulation .22, governing the effective date of the amended regulations, to permit a party with a pending CON Application or CON Exemption to request application of the amended regulations to the review.

"A. A letter of intent or application submitted after the effective date of these regulations is subject to their provisions.

B. Upon request of an applicant for CON or CON Exemption and, if a contested CON review, with the consent of all interested parties or upon a finding of good cause by the reviewer, an application or request pending at the time these regulations become effective shall be subject to their provisions. If the applicable review criteria have materially changed as a result of these regulations, the application of these regulations to a pending CON application shall be deemed a modification and be governed by Regulation .08E.

~~B.~~ C. . . ."

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Thank you for your consideration of these comments. Please contact me if you have any questions.

Sincerely,

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cc: Kristin Jones Bryce
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