EXHIBIT 1

UNIVERSITY of MARYLAND
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August 14, 2023

VIA EMAIL

Caitlin E. Tepe
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215
caitlin.tepe@maryland.gov

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

Dear Ms. Tepe:

I write on behalf of the University of Maryland Medical System ("UMMS") to provide formal 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 formal review and comment via the Maryland Register on July 14, 2023 (the "Proposed Regulations").

UMMS appreciates the Commission staff's review and adoption of informal comments suggested by UMMS and others, in a revised draft of the procedural regulations recirculated for formal comment. As noted by the Commission staff in its summary of the informal comments, the revisions to the Commission's procedural regulations arise from the MHCC CON Modernization Task Force, Governor Hogan's 2015 Regulatory Reform Commission, and significant changes to enabling statute since the procedural regulations were last amended. Further, the 2018 Final Report on Modernization of the Maryland CON Program identified a number of recommendations to streamline the CON review process. Notably, however, many informal comments raised by UMMS and supported by others to accomplish these recommendations, were not addressed in the revised draft regulations or in the Commission staff's summary of the draft regulations.

UMMS urges the Commission to adopt the Proposed Regulations with the modifications discussed below.

General Comments

UMMS provides the following general comments regarding the Proposed Regulations.

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.

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, both of which types of projects 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 and exemptions from CON review under Regulations .03 and .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 exempted from CON review under Proposed Regulation .04.

Comments on Specific Proposed Regulations

Regulation .01, Definitions

"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."

"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."

"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.~~"

"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~~."

"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."

"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."

"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."

Regulation .03, Non-Coverage

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."

Regulation .04, Exemptions from CON Review

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;"

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."

Regulation .08, Procedure for Review of CON Applications

1. 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.

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 . . ."

2. 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."

3. 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)."

Regulation .09, Commission Decision and Action on CON Applications

1. 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. An interested party filing exceptions opposing a recommended project approval shall have previously filed written comments in accordance with Regulation .08F(1)(c)-(d)."

Regulation .10, Miscellaneous Rules and Procedures

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 also 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."

Regulation .11, Evidentiary Hearings

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."

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."

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 exempted from CON review under Proposed Regulation .04. Applicants obtaining Commission approval for projects 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. 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."

Regulation .13, Certificate of Conformance and Ongoing Performance

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. 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."

Regulation .14, Special Procedures

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."

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. 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."

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."

* * *

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

Sincerely,

Aaron J. Rabinowitz
Senior Vice President, General Counsel
University of Maryland Medical System

cc: Kristin Jones Bryce
Senior Vice President and Chief External Affairs Officer
University of Maryland Medical System

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August 14, 2023

Caitlin E. Tepe, Assistant Attorney General
Alexa Bertinelli, Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
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Re: **Comments on Proposed Amendments to COMAR 10.24.01**

Dear Ms. Tepe and Ms. Bertinelli:

Thank you for the opportunity to participate in the process of amending the certificate of need ("CON") regulations proposed by the Maryland Health Care Commission ("MHCC"). We are aware of the comments being submitted by our client, Health Facilities Association of Maryland ("HFAM"), and support them without reiterating them to avoid duplication.

We previously submitted informal comments in letters dated September 19, 2022 and February 23, 2023 regarding the previous drafts of proposed regulatory changes. We also participated in the February 9 Webinar in which a number of topics were discussed in-depth, but where time did not permit a discussion of all comments we and others submitted. We are pleased to note that some of our prior suggestions were incorporated into the proposed regulations published in Issue 14 of the July 14, 2023, Maryland Register. There were comments made previously which are not addressed in the proposed regulations. We repeat those comments here, and ask that they be considered:

Definitions: Section .01

.01B(35)(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 even if it is not within the service area of the replacement acute care hospital.

.01B(35)(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(50)(a)(iv): Why are pharmacy benefit managers included within this definition of a third-party payer seeking Participating Entity status?

.01B(60)(c): The reference to an evidentiary hearing should include the phrase "if any."
.01B after (60): 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)(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(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.

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 before any such regulation is adopted including whether there a statutory basis for this change. This is a major change to the CON process that will add cost and increase workload among facilities and the Commission staff alike. The statute reflects legislative intent to create paths for certain types of projects outside the CON process, such as merged asset system projects that qualify for exemptions, certificates of conformance, and similar processes. It is contrary to that legislative intent to create a broad and general reference to "approvals" that includes references to projects legislatively separate from the CON process.

First Use: Section .18

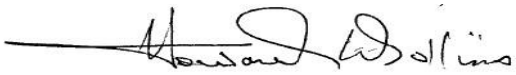
Here too, the scope of the draft regulations relating to approvals other than a CON merits substantial discussion. Currently First Use Approval is a concept used in relation to the CON process. There can be a major effect on the timing and implementation of other forms of projects if First Use concepts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

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.

Sincerely,



Howard L. Sollins

John J. Eller

HFAM
Health Facilities Association of Maryland
Partners in Quality Care

August 14, 2023

Caitlin E. Tepe
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: **Comments on Proposed Action to COMAR 10.24.01**

Dear Ms. Tepe:

On behalf of the Health Facilities Association of Maryland ("HFAM"), we thank the Maryland Health Care Commission (the "Commission") for the opportunity to participate in the process of amending the certificate of need ("CON") regulations.

HFAM has been an active participant in this collaborative process to update COMAR 10.24.01 and has both participated in public stakeholder meetings and submitted formal comments via letters dated September 16, 2022 and February 23, 2023. The members and leaders of HFAM appreciate that some of our suggestions regarding the First and Second Draft of proposed regulatory changes have been incorporated into the proposed regulations published in Issue 14 of the July 14, 2023 Maryland Register.

While some of our comments have been addressed in public meetings or updated in the published regulations, we re-iterate our most recent unclarified and unaddressed comments below and ask that they be reconsidered:

Regarding Regulation .01B (44) which addresses an "entity" that would qualify for merger/consolidation approval, a change was proposed in the Second Draft to allow a merged asset system to include an entity with common ownership "or control."

There are presently some major merged asset systems in Maryland that previously have obtained merger/consolidation approvals. Based on the Webinar, we did not have the impression that the Commission is seeking to change or narrow the definition of merged asset system. To avoid confusion, we suggest the term used by the applicable statute be used in this regulation instead of a reference to an "entity." Under Health-General Article, Section 19-120(a)(2) the statute refers to an "organization" that operates more than one health care facility or operates a health care facility and holds a CON to construct a health care facility. "Organization" is the appropriate term.

Regulation .07A (2) was modified to permit more flexibility in Letters of Intent submitted on behalf of entities not yet formed. We had asked for flexibility in allowing minor changes among owners of the

applicant entity, and it is not clear from the revised language whether such changes would be permissible. Clarification of the language is recommended.

Regulation .09B (2) addresses the timing of exceptions. The increased time permitted for filing and replies is welcomed but does not include language that previously existed that required such filings to be made at least 10 days before the next Commission meeting. Without such language, there would not be sufficient time for all filings to be properly considered by the parties, and preparation for responses to be made at the Commission meeting at which those filings would be considered.

Regulation .10 deals with the new concept of a "Consent Agenda." Though additional language has been added regarding the implementation of a Consent Agenda, there does not appear to be a definition of a Consent Agenda, and no justification has been provided for the establishment of a Consent Agenda. This is a concern because important dealings of the Commission could occur outside of a public forum, which is not consistent with the notion of open meetings allowing the public (including applicants) to learn about concerns and issues of importance to the Commission.

Regulation .12 deals with the new notion of "Holder" Responsibilities, which generated many comments from providers, and was the subject of in-depth discussion during the Webinar. The primary justification for the requirements to be imposed on a Holder that was articulated by Mr. Parker during the Webinar was that the Staff is thinking that exemptions are a form of CON approval and all similar projects including those subject to CON requirements should be treated the same.

The expressed desire is to achieve a procedural equivalency among different forms of approval (i.e., procedural equivalency for merged asset system applicants which are eligible for a merger/consolidation exemption from CON, and non-merged asset system applicants which are not eligible).

However, a different form of approval for merged asset systems outside the CON application process is exactly what is codified in statute. It was the expressed intention of the Maryland legislature to create a process that is exempt from the CON process and instead require merged asset systems to be subject to a different process exempt from CON because the changes are among existing facilities and services.

There was legislative support for such integration and efficiencies, without the constraints of the post approval process applicable to CON approvals. In our view, the draft regulations would contradict the existing statutory authority. This topic needs significantly more discussion and consideration, both as to the underlying justification for the proposed changes as well as the problematic mechanics of implementation (e.g., imposition of and compliance with performance requirements; progress reporting; dealing with project changes after approval) that were addressed in detailed comments previously made.

Finally, there were many other previously offered comments by HFAM that have not been discussed, nor updated in the published version of the proposed changes. For your convenience, we are repeating here those comments which have not been addressed. We ask that these comments be reconsidered.

<u>Definitions: Section .01</u>

.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(26)(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(34)(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(38)(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.

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

.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.

.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 (5): 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 (9): 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.

Preapplication Procedures: Section .07

.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

.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

.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

.10G (1): There are various references here and in the draft regulation to 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.

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.

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

Special Procedures: Section 14

.14A (2): Given the 30-day process for Executive Director review, the regulations should require the agency to 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.

Thank you for your consideration. We appreciate the opportunity for HFAM to participate in the further development of CON regulations outlined in COMAR 10.24.01.

Be well,

Joseph DeMattos, MA
President and CEO

cc: Ben Steffen, Executive Director, MHCC
Wynee Hawk, MHCC
Jeanne-Marie Gawel, MHCC
Alexa Bertinelli, Esq., Assistant Attorney General, MHCC

The Honorable Adrienne Jones, Speaker, Maryland House of Delegates
The Honorable Bill Ferguson, President, Maryland Senate
HFAM Board of Directors