APPENDIX 1

COMAR 10.24.01
Formal Comments: Staff's Analysis and Recommendation

The Maryland Health Care Commission (MHCC or Commission) received comments on the proposed regulations from the University of Maryland Medical System (UMMS), the Health Facilities Association of Maryland (HFAM), and Howard Sollins and John Eller of Baker Donelson (Baker Donelson). This memorandum contains staff's analysis and recommendation in response to the formal comments received.

General Comments:

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

All commenters submitted comments regarding the extension of post-approval requirements to projects approved through an exemption from CON review or certificate of conformance. This change impacts numerous regulations in the chapter, including regulations .02, .12, and .17. In addition to comments about specific sections of the proposed regulations, the commenters raised the general concerns below.

UMMS: "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."

Baker Donelson: "[T]here 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."

HFAM: "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."

Staff Analysis and Recommendation

The proposed regulations introduce the term "holder," defined as "the applicant or applicants to whom the Commission awarded a Certificate of Need, an exemption from Certificate of Need, or other Commission approval for a project that has not received first use approval nor, if necessary, a license from the Department for that project." "Other Commission approval" is defined in the proposed regulations as "approval of a Certificate of Conformance, Certificate of Ongoing Performance, or an exemption from CON review." The term "holder" does not apply to projects that are excepted from CON review under Regulation .03.

The purpose of the new term was to distinguish between the responsibilities of an applicant before and after a CON or other Commission approval has been awarded. The change was also intended to make clear that the post-approval procedures outlined in the regulations apply not just to CON projects, but also projects that are approved as an exemption from CON review under Regulation .04 or as a certificate of conformance under Regulation .13. The term in no way alters the process prior to Commission approval. Therefore, projects that qualify for an exemption from CON review still undergo a streamlined review process prior to approval, which excludes interested parties, has modified review criteria, and imposes shortened timeframes for review.

The Commission is required to promote cost containment strategies and an efficient health care system and has been granted broad statutory authority over its health planning functions. Md. Code Ann., Health-Gen. § 19-103. Projects that are approved as exemptions from CON review are often the same type of health care facility projects that require CON review, with the same scope and impact. The only reason the review process is different is because the applicants are organized as part of multi-facility systems, not because they are smaller or less consequential projects. It is important to monitor projects approved as exemptions or certificates of conformance, and that the projects are timely completed and adhere to the approved budgets. The proposed regulations are less burdensome and incorporate greater flexibility into the post-review monitoring of CONs and other Commission approvals to account for projects of different scope.

The current regulations do not have specified procedures for monitoring or approving changes to non-CON projects after Commission approval. As a result, the Commission has applied the procedures specified in Regulations .12 and .17 to projects approved as an exemption from CON review. *See*, *e.g., In the Matter of Conversion of University of Maryland Laurel Regional Hospital to a Freestanding Medical Facility,* Dkt. No. 18-16-EX002 (July 21, 2022). The changes in the proposed regulations are intended to clarify the Commission's practice and position that the performance standards and the project change process, as well as requests for reconsideration of Commission decisions, should apply equally to CONs and other Commission approvals.

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

UMMS: "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."

Staff Analysis and Recommendation

A specific regulation addressing motions under seal is unnecessary. Applications for CON often contain financial information that is relevant to meet the standards and necessary for interested party review. Staff has due process concerns if applicants were allowed to routinely shield information during the review process. The proposed regulations allow an applicant to file a motion at any time under Regulation .10C. If an applicant has concerns about confidential information, it is permitted to request the Commission maintain that confidentiality. There is no need for duplicative motion regulations.

In addition, UMMS proposed language is based on Maryland Rule of Civil Procedure 2-403, which addresses a party's ability to seek an order from the court to protect the party from discovery that is an annoyance, embarrassment, oppression, or undue burden or expense. That rule addresses a different issue. Any review of a motion to seal would need to consider the Commission's obligations under the Maryland Public Information Act, which favors disclosure of public records, and due process concerns for interested parties.

Regulation .01 Definitions:

"Adversely affected"

UMMS: "[T]he Commission [should] 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)."

Staff Analysis and Recommendation

"Adversely affected" is used in the procedural regulations for determining whether a person qualifies as an interested party in the review of a CON application. In the proposed regulations, MHCC has already imposed greater limits on who qualifies as an interested party by requiring a person seeking interested party status to demonstrate potential negative impact from the proposed project.

UMMS's proposals would impose greater limitations on who qualifies as an interested party. Existing providers who are recognized as interested parties serve a valuable role and provide an important perspective in evaluating whether a CON application has met all required criteria. Recognizing interested parties from contiguous planning regions is particularly important for projects in rural areas, which can impact multiple planning regions. In addition, UMMS' proposal to change the word "service" to "medical service" is too narrow. The definition of "medical service" excludes several services subject to CON review, such as hospice and home health.

"Affected public"

UMMS: UMMS proposes that the Commission add a definition of "affected public" that requires a showing of adverse impact.

Staff Analysis and Recommendation

The term "affected public" is only used once in the proposed regulations and has a very narrow application. Under §19-120 of the Health-General Article, the Commission can only approve an exemption from CON review if a project is in the "public interest." Under the proposed

regulations, the Commission is required to solicit comments from the "affected public" on exemption requests to assist in its determination whether a project is in the public interest. A definition is not necessary. In addition, UMMS's proposed definition is too limiting because public comments in support of a project would also be relevant in determining whether a project was in the public interest.

"Bed capacity"

UMMS: UMMS provided a proposed definition to align the definition of bed capacity in the procedural regulation with the definition in the State Health Plan chapter for Acute Care Hospitals. UMMS also included the following language in its proposed definition: "For a hospital, bed capacity does not include emergency department treatment space, dedicated observation beds, or other space dedicated for non-medical services."

HFAM: "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."

Staff Analysis and Recommendation

The Commission is in the process of revising its State Health Plan (SHP) chapter for Acute Care Hospitals and intends to align the definition in the chapter with the definition in the proposed COMAR 10.24.01 regulations. The second part of UMMS's suggested definition is unnecessary and would create confusion because it leaves too much discretion to dedicated and undedicated space.

With regard to HFAM's comments, it is not necessary to discuss shell space and surge capacity as part of the definition of "bed capacity." Shell space for hospitals is currently addressed in the associated SHP chapter. The proposed regulations provide an expedited process to obtain an emergency CON to address concerns about surge capacity.

"Health care facility"

HFAM: "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)."

Staff Analysis and Recommendation

The exception related to a comprehensive care facility on the campus of a continuing care retirement community was not removed, but instead incorporated into the reference to comprehensive care facility at Regulation .01B(26)(a)(ix): "'Health care facility' means . . . A comprehensive care facility, except as provided by Regulation .03 of this chapter and Health-General Article, §19-114(d)(2), Annotated Code of Maryland."

"Holder"

UMMS: "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."

Staff Analysis and Recommendation

As explained under the General Comments section of this memorandum, staff recommends no change in response to this comment.

"Initiation of construction"

HFAM: "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."

Staff Analysis and Recommendation

The current definition is sufficiently clear that only those permits required to initiate construction are required. This term has limited applicability and is used only in reference to the implementation schedule that an applicant proposes in accordance with Regulation .12A.

"Interested party"

UMMS: "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."

Baker Donelson: "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." Baker Donelson also expressed concern about the removal of the reference to issue areas over which the Commission has jurisdiction from the definition of interested party.

Staff Analysis and Recommendation

The cross-reference to Regulation .08 proposed by UMMS is unnecessary and the proposed regulations are sufficiently clear that a person seeking to be recognized as an interested party must comply with Regulation .08F. Definitions define terms, but do not include regulatory provisions.

In response to the comments raised by Baker Donelson, staff notes that a definition of "regional health system" is included in the proposed regulations. The language in the proposed regulations related to the ability of certain jurisdictions to serve as interested parties in reviews of replacement acute general hospital projects proposed by regional health systems is derived from statute. Md. Code Ann., Health-Gen. § 19-126.

Lastly, the reference to issue areas over which the Commission has jurisdiction was removed from the definition of "interested party" because that language is already incorporated into the definition of "adversely affected."

"Licensed bed capacity"

HFAM: **"**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."

Staff Analysis and Recommendation

As with the definition of "bed capacity," it is not necessary to discuss shell space and surge capacity as part of the definition of "licensed bed capacity." The proposed regulations provide an expedited process to obtain an emergency CON to address concerns about surge capacity.

"Merged asset system"

HFAM: "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."

Staff Analysis and Recommendation

Staff agrees with HFAM's proposal to change the term "entity" to "organization" to align with the statute.

"Participating entity"

UMMS: 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… 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."

Baker Donelson: "Why are pharmacy benefit managers included within this definition of a third-party payer seeking Participating Entity status?"

Staff Analysis and Recommendation

As with the definition of "interested party," it is not necessary or appropriate to cross-reference the requirements for submitting comments under Regulation .08F. In accordance with the Style Manual, definitions define terms and should not include regulatory provisions.

The payors who may qualify as "participating entities" is intended to be broader than payors under the Insurance Article and include unions that provide health benefits for members and pharmacy benefit managers, who may provide an independent standalone benefit.

"Reviewer"

Baker Donelson: "The reference to an evidentiary hearing should include the phrase 'if any.'"

Staff Analysis and Recommendation

Staff agrees with the requested change to reflect that evidentiary hearings are not always held.

"Threshold for capital expenditures"

Baker Donelson: "Why is the definition of 'threshold for capital expenditures' eliminated instead of being updated? Is it simply replaced by the Hospital Capital Threshold definition?"

Staff Analysis and Recommendation

This change reflects a statutory change in 2019 that repealed the requirement for a health care facility other than a hospital to obtain a CON prior to making a capital expenditure above a certain threshold.

"Contested review"

UMMS: "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."

Staff Analysis and Recommendation

UMMS comment references a prior informal version of the regulations. The proposed regulations include a definition for "contested review."

Regulation .02 Coverage

.02A(3) The bed capacity of a health care facility is changed

HFAM: "The reasons for the removal of the text from the reference to changes in bed capacity are unclear…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."

Staff Analysis and Recommendation

Regulation .02 specifies the projects for which a CON must be obtained "[e]xcept as provided in Regulations .03—.05 of this chapter or as otherwise provided by law." The specific exception from CON referenced by HFAM permitting certain changes in bed capacity is retained in Regulation .03.

Regulation .03 Non-Coverage by Certificate of Need or Other Commission Approval

.03B(1) In addition to providing the information in §A of this regulation, a person seeking to acquire a comprehensive care facility, home health agency, or hospice shall:

- **Identify each person with an ownership interest in the acquiring entity or a related or affiliated entity, including**
  - **The percentage of ownership interest of each such person; and**

HFAM: "To be consistent with Medicare process, disclosures at 5% or above should be the standard."

Staff Analysis and Recommendation

In pursuit of greater transparency in nursing home acquisitions, Chapter 288 (Senate Bill 509 of 2023) requires the collection of more information about the ownership interests of the acquiring entity. The Commission is acting in accordance with the new responsibilities under Health General 19-115.

.03B(1)(b): (b) Provide information on corporate structure and affiliations of the acquirer, purchase price, source of funds, and other relevant data as requested;

HFAM: "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."

Staff Analysis and Recommendation

Similar to the information about ownership interests, information about the purchase price of acquisitions provides greater transparency to the Commission in evaluation of acquisitions.

.03C Closure of a Health Care Facility.

HFAM: "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."

Staff Analysis and Recommendation

Under Health-Gen. § 19-120(l)(3), the Commission has the authority to require a health care facility other than a hospital to hold a public informational hearing prior to its closing or partial closing. The proposed regulations incorporate statutory language. Neither the statute nor the proposed regulations require a public informational hearing to be held in all circumstances.

.03D(5) A health care facility shall not request authorization by the Commission to temporarily delicense bed capacity or the entire health care facility or to temporarily suspend a CON-approved service more than one time in a 12- month period.

HFAM: "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."

Staff Analysis and Recommendation

The current limit of temporary delicensure requests is necessary to ensure reasonable oversight of existing licensed bed capacity. MHCC, the Office of Health Care Quality, and other State agencies, maintain inventories of licensed bed capacity. Permitting more frequent, unlimited requests would be difficult to track, monitor, and maintain a reliable licensed bed inventory.

.03D(9): If, at the end of the one-year period or other time period permitted under this section, the requirements of §C(5) or (7) of this regulation have not been met, no request for an extension of time has been granted pursuant to §C(6) of this regulation, and the previously delicensed bed capacity or facility has not been relicensed or the previously suspend service has not been reimplemented, the bed capacity, health care facility or service is deemed abandoned by its owner or operator.

HFAM: 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.

Staff Analysis and Recommendation

Staff agrees with HFAM's suggestions and has added back language requiring notice of the deemed abandonment.

.03G "A CON is not required for a non-hospital health care facility project by a health maintenance organization if…"

UMMS: **"**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."

Staff Analysis and Recommendation

Staff has identified only one HMO in Maryland to which this exception would apply and is not aware of any violations of the threshold limits or obtaining a "competitive advantage" as UMMS alleges. Given the limited scale of this exception, an annual survey specific to this question is unnecessary.

.03J(2) After 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.

Baker Donelson: 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?

Staff Analysis and Recommendation

The language in the proposed regulation is not discretionary and requires the Commission to consult with the Health Services Cost Review Commission for any request by a hospital from an exception from CON review for a capital expenditure in excess of the threshold.

.04 Exemption from Certificate of Need Review

.04A(2): Relocation of an existing health care facility owned or controlled by a merged asset system…

UMMS: 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 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;"

Staff Analysis and Recommendation

Staff agrees that a change to this section is necessary because the definition of "primary service area" is limited to hospitals and proposes revised language consistent with Regulation .03E.

.04C(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.

UMMS: "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."

Staff Analysis and Recommendation

Pursuant to §19-120 of the Health-General Article, the Commission can only approve an exemption from CON review if a project is in the "public interest." Under the proposed regulations, the Commission is required to solicit comments from the "affected public" on exemption requests to assist in its determination whether a project is in the public interest. The proposed regulations as written do not confer interested party status to a member of the public that submits comments on an exemption request and further clarity on this point is not necessary. In addition, UMMS's proposed definition of "affected public" is too limiting because public comments in support of a project would also be relevant in determining whether a project was in the public interest.

.04D(3)(f) Within ten business days after the public informational hearing, the hospital shall make available on its website a recording of the public informational meeting and provide a written summary of the hearing, which shall also be provided to…

Baker Donelson: "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."

Staff Analysis and Recommendation

All that is required by this regulation is for the hospital to post a recording of the public informational hearing on its website and provide a written summary of the hearing within 10 business days. That is sufficient time for a hospital to comply.

Regulation .08

.08E. Modifications to Letters of Intent and Applications.

UMMS: "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."

HFAM: "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."

Staff Analysis and Recommendation

Rather than specifying the modifications that may be permitted beyond 45 days after docking of an application, the proposed regulations allow for modifications upon a showing of "good cause."

.08F(3) Response to Comments.

HFAM: "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."

Staff Analysis and Recommendation

Additional pages are not necessary. In reviews in which there have been multiple interested parties, the comments submitted have often been repetitive and raised similar or overlapping issues.

.08G(3)(d) "Project Financial Feasibility and Facility or Program Viability. The Commission shall consider the availability of resources necessary to implement the project and the availability of 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."

UMMS: 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 non financial resources, including community support, may be considered, UMMS believes that potential parties and the Commission are better served by clarity on this issue…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."

Staff Analysis and Recommendation

Staff previously addressed the concern about including expansions of an existing service and amended the proposed regulation. Staff believes UMMS was referring to a previous draft. The regulation as drafted would allow applicants to include all relevant resources including non-financial resources and community support. As written, MHCC may consider all relevant sources as part of the evaluation under "resources." The language should remain unchanged as it allows applicants the flexibility to submit a variety of resources applicable to implement the project.

.08G(3)(e): Compliance with 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.

HFAM: .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.

Staff Analysis and Recommendation

The word "terms" is the existing text of the regulation. This is not a new "term of art." Staff updated the title to be consistent with the body.

.08G(3)(f) Project Impact. The Commission shall consider the impact of the proposed project on the costs and charges of existing providers of the facilities and services included in the project and on access to those facilities and services in the service area of the project.

UMMS: 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)."

Staff Analysis and Recommendation

UMMS was referring to a previous draft and these comments have been addressed. As written, the regulation directs the Commission to consider the impact on other providers and gives the Commission the express authority to consider the impact. The proposed regulations also include a definition of "service area."

.09 Commission Decision and Action on CON applications

.09(B) Exceptions:

UMMS: 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. "(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)."

Staff Analysis and Recommendation

The regulations require a party to file written comments in accordance with Regulation .08F(1)(c)-(d) before they can be recognized as an interested party. Staff does not believe it is necessary to repeat those requirements.

.09B(2) Schedule: (a) A proposed decision in a contested or comparative review shall be issued at least 30 days before the Commission meeting at which the proposed decision and order will be considered. (b) 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. (c) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff in a contested or comparative review shall specify that exceptions shall be filed on a date at least 10 days after the issuance of a proposed decision and any response to the exceptions filed on a date at least 7 days after the filing of exceptions.

HFAM: 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.

Staff Analysis and Recommendation

The proposed regulations require the staff or reviewer to issue a staff report or proposed decision 30 days before the Commission meeting at which it will be heard along with a schedule for exceptions. The proposed regulations require that the schedule issued by staff must allow at least 10 days for exceptions to be filed and at least 7 days to respond. Staff recommends minor changes to the proposed regulations to clarify that staff will set the date on which exceptions and responses are due. Because the staff report or proposed decision will be issued 30 days prior to the meeting, there will be sufficient time for all parties to file exceptions and responses.

.09B (3): Responses to exceptions shall be limited to 15 pages, double-spaced, excluding attachments.

UMMS: 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.

Staff Analysis and Recommendation

Additional pages are not necessary and the limits under the current restrictions will reduce repetition.

09C: ~~(3) This section does not: (a) Confer interested party status or aggrieved party status upon a participating entity; or (b) Grant a participating entity the right to judicial appeal under State Government Article, Title 10, Annotated Code of Maryland.~~

UMMS: 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.

Staff Analysis and Recommendation

The definitions are clear that participating entities do not have the right to appeal because they are not aggrieved parties. It is unnecessary to repeat it again in this section.

Regulation .10, Miscellaneous Rules and Procedures.

.10C: Motions Practice.

UMMS: UMMS proposed that Regulation .10C(5) be changed from five days to fifteen days to file an answer to motion and that Regulation

Staff Analysis and Recommendation

As currently drafted, the applicant or interested party has ten days to file an answer to the motion. This is an extension of time from the current five day deadline.

.10D: Summary Decision

UMMS: UMMS proposed that an applicant be provided with fifteen days to respond to a staff's motion for summary decision to deny an application.

Staff Analysis and Recommendation

The proposed regulations already provide fifteen days. UMMS may have been referring to a previous draft of the regulations.

.10G (1): (1) Except in emergency circumstances posing a threat to public health, all decisions of the Commission on an application for a Certificate of Need shall be consistent with applicable State Health Plan standards and criteria established by the Commission.

HFAM: "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."

Staff Analysis and Recommendation

The language of this regulation comes directly from Health- General 19-126(c)(1): "All decisions of the Commission on an application for a certificate of need, except in emergency circumstances posing a threat to public health, shall be consistent with the State health plan and the standards for review established by the Commission." All of the references to "consistent" or "not inconsistent" throughout the proposed regulations mirror the statutes. Staff interpret "not inconsistent" as being more broad than "consistent."

.10K:Consent Agenda

HFAM: 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.

Staff Analysis and Recommendation

The consent agenda was created to streamline meetings on limited, specific issues that would not routinely generate discussions. A Commissioner has the opportunity to remove any item on the consent agenda to the main agenda or next scheduled meeting. The consent agenda does not create opportunities for the Commission to conduct public business "outside of a public forum" as the consent agenda still occurs during the public meeting.

.10(X)* Motion for Protective Order; Production of Information under Seal.

UMMS: "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."

Staff Analysis and Recommendation

As stated under the General Comments of this memorandum, an applicant can file a motion at any time under Regulation .10C. A specific process for motions under seal is not necessary.

Regulation .11 Evidentiary Hearings

.11A. Request for Evidentiary Hearing.

UMMS: "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."

HFAM: "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."

Staff Analysis and Recommendation

The current language in the proposed regulations does not result in fewer rights for an evidentiary hearing in reviews for the addition of services. The definition of "health care facility" includes "[o]ther health institutions, services, or programs that may be specified as requiring a CON under State law." COMAR 10.24.01.01; Health-Gen. § 19-114(d)(1)(ix).

In addition, it is unnecessary to retain language regarding oral arguments on whether to hold an evidentiary hearing and the ability to appeal an adverse decision. The proposed regulations

streamline the process based on the experience that evidentiary hearings are permitted in very limited circumstances and rarely held. An applicant or interested party retains the right to challenge a proposed decision on a CON application through the filing of exceptions and can raise a denial of a request for an evidentiary hearing at that time.

.11B(1)(a)(i): (a) If an evidentiary hearing is held in accordance with this chapter, the reviewer shall: (i) Conduct a full, fair, and impartial hearing;

HFAM: The word "full" in relation to a hearing is unclear.

Staff Analysis and Recommendation

Staff interprets the word "full" as requiring the reviewer to conduct the hearing in accordance with the procedures outlined later in the regulation, including those related to testimony and witnesses.

.11B(1)(b)(iv): (b) A reviewer has the power to regulate the course of an evidentiary hearing and the conduct of the parties and authorized representatives, including the power to: (iv) Examine witnesses and call witnesses as necessary to ensure a full and complete record;

HFAM: 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.

Staff Analysis and Recommendation

The reviewer is a fact finder in CON reviews and should retain the ability to investigate facts necessary to making a proposed decision. The current and proposed regulations permit the Commission to consider in its review of a CON application "information gathered during the Commission's review of the application, to which each applicant and interested party has been afforded the opportunity to respond." COMAR 10.24.01.08G.

.11B (4): The prehearing conference and the hearing shall be recorded. If an applicant or other person desires a transcript, that person shall pay all costs to transcribe the recording.

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

Staff Analysis and Recommendation

HFAM's requested change is not necessary and the Commission does not want to mediate disputes between parties about transcription costs. If the parties would like to split the cost of transcribing the recording, they are welcome to do so.

.11D List of Genuine Issues

UMMS: "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."

Staff Analysis and Recommendation

Staff disagrees that the proposed regulations broaden the potential scope of review. The language proposed by UMMS and currently contained in the current regulations is equally broad because §D(2)(b)(iv) permits an evidentiary hearing on issues for which the reviewer determines that testimony on an issue would be useful in rendering a decision.

Regulation.12 Holder Responsibilities and Withdrawal of a Certificate of Need or Other Commission Approval.

HFAM: "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."

Staff Analysis and Recommendation

As explained under the General Comments section of this memorandum, staff recommends no change in response to this comment.

.12A Post implementation schedule

UMMS: "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

Staff Analysis and Recommendation

Staff does not recommend changing the definition of holder and therefore this additional change is unnecessary.

.12E: Grounds for Withdrawal of Commission Approval

UMMS: 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: Add: The holder or a person receiving other Commission approval for a project (for E1-5).

Staff Analysis and Recommendation

Staff does not recommend changing the definition of holder and therefore this additional change is unnecessary.

.12G: Final action by the Commission withdrawing a CON or other approval

UMMS: 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."

Staff Analysis and Recommendation

Staff does not recommend changing the definition of holder and therefore this additional change is unnecessary.

Regulation .13 Procedures for Certificate of Conformance and Certificate of Ongoing Performance Applications.

.13C: Completeness Review of Certificate of Conformance Applications.

UMMS: "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.'"

Staff Analysis and Recommendation

UMMS comment refers to a prior draft of the regulations that was released informally. This language is not in the proposed regulations.

.**13C: Completeness Review of Certificate of Conformance Applications.**

UMMS: "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…. 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."

Staff Analysis and Recommendation

UMMS comment refers to a prior draft of the regulations that was released informally. The proposed regulations remove language that permit staff to request additional information beyond that required to make the application complete and limits requests for additional information to information "material to the determination of whether the applicant has satisfied the criteria and

standards for approval." These changes sufficiently streamline the completeness process for certificate of conformance reviews.

.13J: Approval of Applications with Conditions

UMMS: "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."

Staff Analysis and Recommendation

Staff disagrees that the Commission is exceeding its statutory authority. The Commission has broad authority over the development of a health regulatory system. Health-Gen § 19-103. Further, Health-Gen § 19-120.1 anticipates that the Commission could impose conditions on certificates of conformance and ongoing performance by requiring the Commission to impose a condition that an acute general hospital relinquish its authority to provide cardiac services if the hospital fails to meet the Commission's standards. The statute does not restrict the Commission's ability to impose conditions.

Regulation .14 Special Procedures

.14A: Determination of Coverage

UMMS: "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."

Staff Analysis and Recommendation

It is not appropriate to add deemed approvals for all determinations of coverage because it may result in a project being inappropriately excepted from CON review. Staff has added deemed approval language to Regulation .03 for specific types of requests in which it is unlikely that CON review would be required.

.14A: The Executive Director of the Commission shall review the request and act on it within 30 business days of receipt of complete information

HFAM: "Given the 30-day process for Executive Director review, the regulations should require the agency to provide confirmation of receipt of the determination request.**"**

Staff Analysis and Recommendation

Given the fast turnaround time, confirmation of receipt is not necessary.

Regulation .17 Project Changes After Commission Approval

Baker Donelson: "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 is 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."

Staff Analysis and Recommendation

The project change approval process is an abbreviated process that permits the Commission to approve changes to a proposed project without requiring the holder to re-submit to the full review process. The Commission currently applies this process to changes in exemption requests and applications for certificate of conformance. Applying Regulation .17 to exemptions streamlines the process for obtaining approval of changes to these types of projects. The alternative would be to require the project to re-submit to the full exemption review process outlined in Regulation .04 or certificate of conformance review under Regulation .13.

.17A: Filing of Request

UMMS: "[I]nterested 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."

Staff Analysis and Recommendation

The project change approval process is limited to certain types of changes after a CON is approved. Interested parties and participating entities have no role in project change requests and notice is therefore unnecessary.

.17B(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 from the application submission date to the date of the filing of a request for a project change;

UMMS: "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…"

HFAM: "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."

Staff Analysis and Recommendation

The current language is appropriate. The IHS Markit Index is Commission's calculations posted on the website for convenience and if it is out of date, a holder can purchase the IHS Markit Index to conduct calculations. The proposed regulations allow for flexibility by permitting the Commission to use alternate guidance published on its website for calculating inflation.

.17D: Commission Action.

UMMS: "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." 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…."

Staff Analysis and Recommendation

Staff does not recommend the requested change because there are too many factors and variables associated with Commission approvals and project changes. For certain changes, the Commission consults with HSCRC about the requested change, which can delay the review process. The project change process is already an abbreviated process and deemed approval language is not appropriate or necessary.

Regulation .18 Review Required before Licensing and First Use of Project

UMMS: 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: "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…"

Baker Donelson: "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."

HFAM: "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."

Staff Analysis and Recommendation

As discussed throughout these comments, there are a variety of legitimate reasons to monitor non-CON projects approved by the Commission. The Commission is required to promote cost containment strategies and an efficient health care system. Projects that are approved as exemptions from CON review are often the same type of health care facility projects that require CON review, with the same scope and impact. The only reason the review process is different is because the applicants are organized as part of multi-facility systems, not because they are smaller or less consequential projects. It is important to monitor that exemption projects are timely completed and adhere to their approved budgets.

.18A(1): Request for First Use Review and Approval.

UMMS: Should be amended to reflect actual construction projects. Documentation of final construction costs cannot be provided before a project is completed.

Staff Analysis and Recommendation

An applicant files First Use when the project is complete and ready to be operational. The applicant should be able to provide the final accounting of that portion of the project when applying for First Use.

.18A(2) A request for first use approval…the request shall include: (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.

UMMS: The Request for First Use should incorporate any project changes approved under regulation. UMMS proposed the following language: The Request shall include: (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.

Staff Analysis and Recommendation

The additional language proposed by UMMS is not necessary. As stated in Regulation .17, an approved project change is incorporated into a modified CON or other modified approval for the project with conditions as appropriate.

Regulation .20 Emergency Certificate of Need

.20B: (1) A health care facility may apply for an emergency CON by sending a signed letter in PDF format by email and hard copy to the Executive Director that contains:

Baker Donelson: "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."

Staff Analysis and Recommendation

Staff require a hard copy for all filings for numerous reasons including that they are easier to read, it provides a safeguard in case the recipient of the email is unavailable or no longer works at MHCC, or if internet access or other databases become restricted or unavailable. A situation which would enable an emergency CON could also include many of these scenarios necessitating the need for a hard copy to be mailed.