UNIVERSITY of MARYLAND
MEDICAL SYSTEM

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January 26, 2018

VIA EMAIL

Paul.Parker@maryland.gov
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Paul Parker, Director
Center for Health Care Facilities and Development
c/o Ms. Ruby Potter
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: ***Modernization of Certificate of Need Program***

Dear Mr. Parker,

I write on behalf of the University of Maryland Medical System ("UMMS") in response to the Maryland Health Care Commission's November 21st request for comment on the modernization of Maryland's Certificate of Need ("CON") system. As the Commission is aware, UMMS is a university-based health care system that delivers care at more than 150 locations, including the academic University of Maryland Medical Center, eleven community hospitals, and two specialty hospitals, to individuals in central and southern Maryland and the Eastern Shore.

UMMS appreciates the opportunity to comment on the evaluation of modernizing the CON program. The comments enclosed with this letter represent the joint collaboration and consensus of the fourteen hospitals within UMMS. As reflected in the comments, UMMS supports the continuation of a modernized CON program that is more narrowly tailored than existing regulation both in the scope of projects requiring a CON and standards for evaluating CON projects.

Maryland implemented the CON program at a time when less overall regulation of hospitals and hospital services existed and, in particular, the method of regulating hospital revenue was significantly different. The CON process has become, in some ways, an obstacle to hospital planning at a time when hospitals are incentivized under the All-Payer Model between Maryland and the Centers for Medicare & Medicaid Services to seek innovative ways to provide care in lower cost settings. The planning process is often impacted by the unpredictable length and broad scope of CON review. Some of the impediments imposed by the CON process do not come with a corresponding benefit given the existing breadth of regulation of hospitals and health-care spending that exists in Maryland today. A CON process that is narrower in both scope of projects that require review and standards applicable to a review, will allow Commission staff to conduct prompt, narrow, focused reviews of the most significant and impactful health planning projects, while allowing hospitals flexibility in planning as they seek to effect cost-saving changes in the health care delivery system.

As described in more detail in the enclosed comments, UMMS recommends elimination of a CON requirement for: (1) hospital capital projects, (2) the expansion of existing services within a hospital or hospital system, and (3) the establishment of most new services at an existing acute care hospital. UMMS recommends maintaining CON regulation for the establishment of a new general or special hospital, relocation of a hospital, and the establishment of some specialized services. For the remaining CON projects, UMMS recommends that the Commission, and the Maryland General Assembly, streamline the standards used to evaluate projects to standards focused narrowly on need, adverse impact on other providers, access, and, to a limited extent, volume, if volume is clearly correlated with quality for the regulated service.

The CON scope and review process changes that UMMS advocates are not aimed at changing the competitive landscape for hospitals in Maryland, but in making hospital planning more efficient, effective, timely, and less costly. UMMS believes that health care planning concerns addressed by the regulations that UMMS recommends modifying either already are or, with little change could be, more effectively regulated and managed by other agencies, including the Office of Health Care Quality within the Maryland Health Department, and the Maryland Health Services Cost Review Commission.

Thank you for your consideration of these comments.

Sincerely,

Donna L. Jacobs, Esq.
Senior Vice President
Government, Regulatory Affairs and Community Health

cc: Alison Brown

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University of Maryland Medical System Response to MHCC CON Study, 2017-2018, Comment Guidance – Hospital

The University of Maryland Medical System ("UMMS") submits these comments on behalf of itself and the fourteen hospitals within the system in response to the November 21, 2017 request of the Maryland Health Care Commission (the "Commission") for comment on the modernization of Maryland's Certificate of Need ("CON") program. The text of the Commission's survey is copied below in bold italics. UMMS responds under the headings "UMMS Comment."

COMMENT GUIDANCE – HOSPITAL
MHCC CON STUDY, 2017-18

Please consider your answers in the context of Maryland's adoption of global budgets for hospitals, its commitment to achieve the goals of the Triple Aim, and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of hospital CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of hospital CON regulation?

- ☐ ***CON regulation of hospital capital projects should be eliminated.***

  [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 13 to 15.]

- ☑ ***CON regulation of hospital capital projects should be reformed.***

- ☐ ***CON regulation of hospital capital projects should, in general, be maintained in its current form.***

UMMS Comment

[Note: This question refers to "capital projects," but given the surrounding context and comment that a recommendation to eliminate the Certificate of Need ("CON") requirement for capital projects will render many of the following questions moot, UMMS interprets the term hospital capital projects as used to refer to all hospital projects, not only those that require a CON solely because the project cost exceeds the Commission's capital expenditure threshold.]

Maryland adopted and implemented its CON program at a time when the method of regulating hospital rates and revenue differed significantly from the global budget revenue rate-setting methodology ("GBR") of the Maryland Health Services Cost and Review Commission ("HSCRC") that exists today, a response to the All-Payer Model between Maryland and the Centers for Medicare & Medicaid Services ("CMS"). Under the All-Payer Model and GBR rate-setting, hospitals are incentivized to seek innovative ways to provide care in lower cost settings. In addition, because GBR does not include any allowances for capital expenditures, hospitals must seek, and justify, rate changes to the HSCRC in order to have sufficient capital to engage in capital spending above the level of the existing CON capital threshold. In sum, today the HSCRC exercises strong regulatory oversight and control of hospital expenditures.

Considerable regulatory oversight of Maryland hospitals also exists in the arena of patient safety and quality of care. The Office of Health Care Quality ("OHCQ") and The Joint Commission appropriately monitor safety and quality issues, and certain specialized hospital services also adhere to national guidelines.

In light of the incentives of the All-Payer Model and the HSCRC's oversight of hospital budgets, the Commission's oversight of hospital capital expenditures and changes in beds and services is duplicitous and creates delays in the planning process. Of course, if the demonstration project does not meet the benchmarks for renewal and hospital rate-setting changes dramatically in the future, CON regulation of capital expenditures and bed and service changes may once again be an appropriate way to effect measured hospital spending that balances need with costs to payers and the healthcare system. If that should happen in the future, the Commission could recommend that the Maryland General Assembly renew regulation of capital expenditures and changes in beds and services. Under today's regulatory framework, however, the Commission's oversight of many of these hospital projects creates unnecessary procedures that restrict timely and innovative hospital planning.

ISSUES/PROBLEMS

The Impact of CON Regulation on Hospital Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among hospitals?

UMMS Comment

Maryland hospitals collaborate and compete in productive and beneficial ways today, in part because the All-Payer Model encourages collaboration as hospitals work collectively to reduce hospital spending. The scope and review process changes to the CON program that UMMS proposes in these comments are not aimed at changing the competitive landscape for hospitals in Maryland. Rather, UMMS seeks to make hospital planning more efficient, effective, timely, and less costly.

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

UMMS Comment

The CON process does impose barriers to entry for new hospitals and services. As addressed more fully in UMMS' opening comment and in response to Question 4, UMMS posits that barriers for certain services are inappropriate, and stifle hospital planning without a commensurate benefit to the healthcare delivery system. As stated in response to Question 1, UMMS advocates for these changes to make hospital planning more efficient and timely.

3. How does CON regulation stifle innovation in the delivery of hospital services under the current Maryland regulatory scheme in which hospital rate-setting plays such a pivotal role?

UMMS Comment

Some CON regulations are duplicitous and unnecessary in light of Maryland's current regulatory scheme for hospital rate-setting. The All-Payer Model and GBR system incentivize hospitals to encourage care in lower cost settings. Currently, however, Maryland's CON program restricts hospitals seeking to provide alternatives for hospital emergency or inpatient care, such as through the establishment of ambulatory surgical facilities and freestanding medical facilities. Strict regulation of such facilities and the length and uncertainty of the CON review process impose barriers and impede hospital innovation on how to most effectively reduce spending while improving care.

In addition, as addressed more fully in UMMS' opening comment and in response to Question 4, CON review of many hospital projects is duplicitous in light of hospital rate-setting. As addressed more fully in response to Question 9, concerning the State Health Plan chapters, and Question 11, concerning General Review Criteria, the Commission's review of criteria and standards involving the financial aspects of a regulated project, such as financial feasibility, viability, and cost-effectiveness, are also duplicitous and unnecessary in light of the strong role of the HSCRC in approving hospital rates and budgets.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish or relocate a hospital, expand bed capacity or operating room capacity at a hospital, introduce certain services at a hospital, or undertake capital projects that exceed a specified expenditure threshold. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.24.01.02 - .04, which can be accessed at:

http :// www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=l0.24.01.*

4. Should the scope of CON regulation be changed?

A. Are there hospital projects that require approval by the Maryland Health Care Commission that should be deregulated?

UMMS Comment

As described in response to Question 3, under the All-Payer Model, hospitals are incentivized to plan carefully and reduce the cost of care. Hospitals are also incentivized to consider lower-cost alternatives to inpatient and emergency care. In addition, the OHCQ and The Joint Commission monitor hospital quality. Certain specialized hospital services also adhere to national quality standards. As a result, for hospital services for which quality outcomes are not closely correlated with volume, CON regulation is not necessary.

UMMS urges the deregulation of most CON projects for existing providers, including deregulation of the following projects currently subject to CON review:

- Relocation of an existing health care facility to another site, COMAR § 10.24.01.02.A(2), if the new location is within the facility's existing primary service area;
- Change in the bed capacity of a health care facility, COMAR § 10.24.01.02.A(3), unless the change is for inpatient psychiatric services in a

special psychiatric hospital and the provider will no longer be eligible to receive Medicaid reimbursement or payment as a result of the change;

- Change in the type or scope of any health care service offered by a health care facility, COMAR § 10.24.01.02.A(4), and the change:
    - Establishes a new medical service, COMAR § 10.24.01.02.A(4)(a), defined by COMAR § 10.24.01.B(27) as:
        - Any of the following categories of health care services as they appear in the Commission's inventories of service capacity:
            - Medical/surgical/gynecological/addictions;
            - Obstetrics;
            - Pediatrics;
            - Psychiatry, unless the new service will not be eligible for Medicaid payment or reimbursement;
            - Rehabilitation;
            - Chronic care;
            - Comprehensive care;
            - Extended care;
            - Intermediate care; or
            - Residential treatment;
        - A subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of medical services for which the State Health Plan provides a need projection methodology or specific standards (subject to same comment above regarding psychiatric services);
    - Establishes a new neonatal intensive care program, COMAR § 10.24.01.02.A(4)(b) (in part, other programs excluded);
    - Establishes a new home health agency, general hospice care program, or freestanding ambulatory surgical facility, COMAR § 10.24.01.02.A(4)(c);
    - Builds or expands ambulatory surgical capacity in any setting owned or controlled by a hospital, COMAR § 10.24.01.02.A(4)(d);
    - Results in the establishment, expansion, or transfer of ownership of a home health agency or home health care service, COMAR § 10.24.01.02.A(4)(e);

- Closes or temporarily delicenses an existing medical service (and is not otherwise defined under the non-coverage regulation), COMAR § 10.24.01.02.A(4)(f); or
- Closes an existing health care facility or converts it to a non-health-related use COMAR § 10.24.01.02.A(4)(g);

- Capital expenditure by a hospital at any amount, COMAR § 10.24.01.02.A(5);

The proposed deregulation will also require legislative changes.

The deregulation proposed above would render the majority of the regulation under COMAR § 10.24.01.03, Non-Coverage by CON Review Requirements, and § 10.24.01.04, Exemption from CON requirements, moot. If the Commission and Maryland General Assembly do not fully deregulate each of the projects described above, UMMS recommends, in the alternative, that the Commission consider subjecting such projects to the less cumbersome review process of a CON exemption, determination of non-coverage, or some other new form of expedited review process.

UMMS does not recommend deregulation of the following projects currently subject to CON review:

- The establishment of hospital services by new market entrants, *i.e.*, the Commission should continue to regulate whether a "[a] new health care facility" may be "built, developed, or established" pursuant to COMAR § 10.24.01.02.A(1).

- The establishment of a new burn treatment, open heart surgery, or organ transplant surgery program (COMAR § 10.24.01.02.A(4)(b), in part), remain subject to CON review because the there is a recognized correlation between quality outcomes and volume for those services.

- The relocation of an existing health care facility to another site, COMAR § 10.24.01.02.A(2), if the new location is <u>not</u> within the facility's existing primary service area.

- The establishment of a new medical service for psychiatric services (COMAR § 10.24.01.02.A(4)(a); COMAR § 10.24.01.B(27)), or a change in beds of an existing facility providing psychiatric services, if the facility will not be eligible for Medicaid payment or reimbursement.
- The establishment of a freestanding medical facility ("FMF") by an existing acute care provider, where the provider is <u>not</u> establishing an FMF in its primary service

area or is not involved in a process of converting an existing acute care facility to a more limited scope of services.[1]

B. Are there hospital projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

UMMS Comment

UMMS does not believe new CON regulation of currently non-regulated hospital projects is necessary.

The Project Review Process

5. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

UMMS Comment

Some aspects of the CON review process pose significant barriers to hospital planning today because the current process does not allow hospitals to predict the timing, depth, or focus of an individual review. Three "choke-points" in the current process include (i) out-of-date review standards and criteria; (ii) review standards and criteria that are ambiguous or applied inconsistently; and (iii) a lack of clear timeline or enforcement mechanism.

(i) Out-of-date review standards and criteria

Outdated review standards can create a significant waste of resources and time in health care planning. By statute, the State Health Plan must be adopted every five years. Md. Code, Health General Article, § 19-118. Several State Health Plan chapters contain review standards and criteria or need methodologies that are outdated and have not been reviewed or revised in well more than five years. As a result, applicants sometimes must apply for a project without knowing what standards or criteria will be applied to it, or how the Commission will interpret out-of-date standards. The lack of clear standards is an impediment to the planning and application process because applicants may plan a project that the Commission will ultimately determine must be modified to meet the Commission's interpretation of an out-of-date standard – an interpretation that was unknowable to the applicant during the planning and application process. The Commission staff, in turn, spends significant time bringing out-of-date

[1] Under current law, a general hospital may convert to an FMF pursuant to a CON exemption process. COMAR § 10.24.09.04C. UMMS proposes that such a conversion should be deregulated for an existing general hospital where the converted FMF would be located in the converting hospital's primary service area.

review criteria or standards up to date on an ad hoc basis, or creating alternatives, and then must review the project on these bases. This is a waste of resources for all parties.

As an example, applicants sometimes must apply for a project based on a need projection that is several years out of date. The applicant in such a scenario must advocate for a method to update the existing need projection methodology. The Commission staff will either accept the applicant's analysis, or will create their own update. If the applicant does not meet the updated need standard advocated by staff, staff will not recommend applicant's project. If instead the Commission timely updates need projections as required by statute, applicants will know in advance whether their applications are consistent with current need projections. If the projects they are considering exceed those projections, they will be able to direct their resources to other projects without costly and unnecessary delay.

The existence of outdated review standards and criteria may also result in a decision based on sound health care planning policy, but inconsistent with the applicable State Health Plan chapter. In an uncontested review, this may not pose a problem other than the increased uncertainty and potential additional planning costs described above. However, in a contested review, if the Commission grants a CON based on a State Health Plan chapter that includes a review standard that is impractical or impossible to apply because it is out of date, the decision will subject the Commission and the CON applicant to potential legal action by interested parties.

Examples of outdated standards include, but are not limited to:

- COMAR § 10.24.07 – Psychiatric Services – This chapter was last updated in October, 1996 for the five year term 1985-1990. The standards are significantly outdated and it should be replaced.

- COMAR § 10.24.18 – Specialized Health Care Services – Neonatal Intensive Care Services (Effective Feb. 9, 1998; Suppl. 1 Effective Dec. 14, 1998; Suppl. 2 Effective Oct. 23, 2006) – The Commission has not revised this chapter in more than a decade. The Commission should, at a minimum, consider whether the Minimum Volume standard reflects the current standard of care, and review the definitions for potential update based on advancements in the field.

- COMAR 10.24.10 – Acute Care Hospital Services (Effective Jan. 26, 2009) – Standard .04A(3)(b) requires an applicant hospital "with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospital's reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall

document each action it is take to improve performance for that Quality Measure." The Hospital Performance Evaluation Guide has evolved, and has not reported data in a method that would allow a hospital to determine its quartile ranking or compliance level since the measurement timeframe for January 2012 to December 2012. Commission staff has required hospitals instead to report on any quality measures now ranked as "below average" and provide a plan for correction. This is inconsistent with the plain reading of the standard, but strict compliance is also impractical. As a result, applicants are in regulatory limbo, and a decision under this chapter is subject to potential judicial action by an interested party for failure to comply with the State Health Plan.

- 10.24.17 – Specialized Health Care Services – Cardiac Surgery and PCI (Effective Nov. 9, 2015) – In the recent comparative CON review for the establishment of cardiac surgery services in the Upper Shore region, the Commission decision found that Standard .05A(7), Financial Feasibility, was not responsive to the current All-Payer Model and that if strictly interpreted, no applicant could meet the standard. While UMMS disagrees with that interpretation (UM Baltimore Washington Medical Center and UM Prince George's Hospital Center are parties in that case), if this standard remains a part of the Commission's CON review following modernization of the CON program, the Commission should revise the standard to consider the current rate-setting methodology.

(ii) Review standards and criteria that are ambiguous or applied inconsistently

Ambiguity in how compliance with certain standards and criteria will be evaluated and inconsistent evaluation by the Commission furthers the unpredictability of the CON review process. The Commission should publish regulations that make clear how compliance with review standards and criteria will be evaluated.

In addition, any methodologies that the Commission will use to evaluate compliance with a review standard should be published through rulemaking in a transparent process. The use of new methodologies not set forth in Commission regulations creates unpredictability in the planning process and wastes significant resources of applicants who would be better positioned to determine whether to apply for a CON if the Commission published clear guidance on what methodologies would govern a review in advance.

The recent comparative review of applications to establish cardiac surgery services in the Upper Shore region illustrates the inefficiency posed by the inconsistent application of ambiguous standards and the late revelation of methodologies to evaluate compliance with ambiguous standards. The Commission's inconsistent application of

the minimum volume standard in that cardiac surgery review as compared to prior reviews, the lack of clear instruction in the standard itself, and the late revelation of a new methodology to evaluate the standard at the close of the review left the parties without predictability in the process. This has cost the parties and the Commission significant time and resources, and has delayed the establishment of a cardiac surgery program in Anne Arundel County. These issues may have been avoided if review standards and criteria provided clear instruction as to how compliance would be evaluated.[2]

(iii) Lack of clear timeline or enforcement mechanism

CON reviews can take a significant and uncertain amount of time, which can impede efficient hospital planning. The table below depicts the average amount of time between the application date and Commission action for decisions from 2014 to 2017, based on type of review:

CON Service/Project Type	No. Reviews 2014-2017	Average Days from Application to Decision
Certificate of Need Reviews		
COMAR 10.24.07: Psychiatric Services	2	371
COMAR 10.24.08: Nursing Home Services	13	275
COMAR 10.24.10: Acute Care Hospital Services	5	608
COMAR 10.24.11: General Surgical Services	8	179
COMAR 10.24.13: Hospice Services	4	264
COMAR 10.24.14: Alcoholism and Drug Abuse, Intermediate Care Facility Treatment Services	4	562
COMAR 10.24.16: Home Health Agency Services	1	132
COMAR 10.24.17: Specialized Health Care Services - Cardiac Surgery & PCI	1	762
Total CON Reviews, Review Days	**38**	**341**
CON Modification	**10**	**120**
CON Exemption	**5**	**99**

A table containing more information for each review is attached as Appendix 1.

[2] The cardiac surgery review is not the only example where the Commission applied a newly created methodology to evaluate compliance with review standards or criteria at the end of a review, putting the applicant(s) and interested parties in a position where they could not have known at the start of the review how compliance would be measured. The Commission revealed and relied upon new methodologies near the close of reviews in the recent CON projects involving the relocation of Washington Adventist Hospital, Sheppard Pratt at Elkridge, and Prince George's Hospital Center.

This history makes clear that there is little predictability in the timing of CON reviews, and most reviews take longer than the applicant expected. Improvement in both timeline predictability and overall length of time of CON reviews will enable hospitals to engage in more efficient and effective planning.

As discussed more fully in response to other questions, the Commission's review of many CON review standards and criteria is duplicitous with the regulatory control and oversight of OHCQ and HSCRC, as well as the quality monitoring provided by national bodies for certain specialized services. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 4, 11, 14, 17, 24, and 25). Reduction in the scope of projects that require a CON and of the review standards and criteria may allow staff to process applications in a prompt manner. Such changes will require legislative action.

In addition, UMMS recommends imposing more clear regulatory timelines regarding the length of each step of the CON process, and clear guidance as to what relief is available to applicants if the Commission has not met those timelines, such as deemed approvals. Such changes may be accomplished through the regulatory rulemaking process.

6. Should the ability of competing hospitals or other types of providers to formally oppose and appeal decisions on projects be more limited?

UMMS Comment

UMMS believes it would be appropriate to limit the criteria and standards that interested parties are permitted to address to issues directly involving the interested party, such as adverse impact. If volume is correlated with quality for a particular service, it would be appropriate for an interested party to comment on the need for the service. Competing hospital applicants in a comparative review should be permitted to comment on any criteria or standard to the extent that the competing hospital is commenting that its proposal better meets that criteria or standard.

Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

UMMS Comment

UMMS advocates for deregulation of CON projects based solely on the project cost exceeding a capital expenditure threshold. However, should the Commission continue to regulate such projects, UMMS believes it would be appropriate to review them through a truncated CON exemption process.

The exemption review for merged asset systems makes good sense and encourages hospitals to collaborate on cost saving measures. The exemption process should continue to be an option for merged asset systems.

7. Are project completion timelines, i.e., performance requirements for implementing and completing capital projects, realistic and appropriate? (See COMAR 10.24.01.12.)

UMMS Comment

UMMS believes current regulatory performance requirements should be modified to allow greater flexibility that currently exists where the applicant demonstrates good cause. For any project that remains subject to CON review, obstacles may arise in the course of implementing a project that were not foreseen or foreseeable by applicants. The current strict performance requirements do not allow flexibility for such situations. The imposition of inflexible performance requirements could result in a scenario where an applicant who has received a CON based on a determined need (and compliance with met all other criteria and standards) must reapply for a CON for purely procedural reasons, even where the continuance of performance requirements would be noncontroversial. This could impose additional cost and delay on both the applicant and Commission staff without any commensurate benefit.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for hospital facilities and services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

UMMS Comment

As addressed throughout these comments, UMMS believes the Commission's review of any project that remains subject to the CON program should be more limited in scope to issues of need, access, and adverse impact, which would necessitate significant changes in each State Health Plan chapter. Many current regulations concern issues that are already effectively controlled through HSCRC rate-setting and adjustments to GBR, OHCQ licensing and other quality control, and The Joint Commission accreditation and regular survey process. If there is any concern that the removal of quality and financial issues from the CON program would result in insufficient oversight of those issues, adjustments should be made to the regulatory authority of OHCQ and the HSCRC.

In addition, as discussed more fully in response to Question 5, Certain State Health Plan regulations are outdated and should be updated. The paring down of the scope of CON

review would allow the Commission to devote additional resources to more timely updates of State Health Plan chapters and out-of-date need methodologies.

9. Do State Health Plan regulations focus attention on the most important aspects of hospital projects? Please provide specific recommendations if you believe that the regulations miss the mark.

UMMS Comment

UMMS advocates changes to the CON program that would necessitate significant changes to each State Health Plan chapter and the procedural regulations. Even if the Commission does not seek to deregulate the projects identified in response to Question 4, UMMS recommends that the Commission seek to remove several topical areas currently considered by the Commission. UMMS believes that issues involving construction costs, charges, charity care, financial feasibility, and viability, should be within the exclusive regulatory authority of the HSCRC, and that issues involving quality of care, including compliance with quality measures and facility design elements responsive to quality of care issues, should be within the exclusive regulatory authority of OHCQ. UMMS comments below on the State Health Plan chapter for Acute Care Hospital Services for illustrative purposes, and recommends similar changes across all State Health Plan chapters. The deregulation UMMS proposes will require regulatory and legislative changes.

In addition, UMMS notes that different State Health Plan chapters identify standards that appear in all or most chapters, such as financial feasibility, yet these standards, and the method of compliance, are defined differently in different chapters. While some distinction may be necessary based on the different services addressed, some differences in the standards in different chapters do not appear related to the individual service but instead may result merely from the drafting of different chapters at different times. UMMS urges the Commission to define standards similarly across all chapters, such that any differences are for intentional, substantively meaningful purposes.

UMMS also urges the Commission to include guidance and instruction as to how compliance with any standard that remains part of the CON review process will be measured. This will increase the predictability of the CON review process, allowing hospitals to plan more effectively and efficiently, and will protect against the application of inconsistent compliance measures and methodologies in different reviews.

10.24.07 – Psychiatric services. As discussed more fully in response to question 5, this chapter is outdated and should be updated throughout or replaced entirely.

10.24.10 – Acute Care Hospital Services. Many of the review standards within this chapter address concerns that are either already effectively regulated by, or would be better suited for oversight by other agencies.

The HSCRC should exclusively regulate the concerns addressed by the following standards:

- .04A(1) Information regarding charges
- .04A(2) Charity care policy
- 04B(4)Adverse impact, subsection (b) only, concerning rate increase
- 04B(5) Cost Effectiveness
- .04B(7) Construction cost of hospital space
- .04B(8) Construction cost of non-hospital space
- .04B(11) Efficiency
- .04B(13) Financial feasibility.

The OHCQ, with The Joint Commission involvement, should exclusively regulate the concerns addressed by the following standards:

- .04A(3) Quality of care (Note that subsection (b) refers to Quality Measures that are no longer updated. At a minimum, if this issue remains under Commission review, this subsection should be removed or revised.)
- .04B(3) Minimum Average Daily Census for Establishment of Pediatric Unit.)
- .04B(12) Patient safety

The following standards should remain part of Commission's CON review process:

- .04B(1) Geographic Accessibility
- .04B(2) Identification of bed need (However, as noted in response to question 5, UMMS believes certain expansions of beds or new services in existing hospitals should be deregulated entirely.)
- 04B(4) Adverse impact, except that subsection (a) concerning rate increase should be under sole authority of HSCRC
- 04B(6) Burden of proof regarding need
- .04B(14) ED treatment capacity and space
- .04B(15) ED expansion
- .04B(16) Shell space

<u>10.24.11 – General Surgical Services.</u> Should the Commission continue to regulate the addition of surgical capacity at new or existing health care facilities, UMMS recommends, in addition to the general comments above, that the Commission revise the current regulations to employ a more flexible approach to the number of operating rooms that a facility may contain. The costs associated with an additional operating room have minimal impact on the healthcare delivery system. Thus, considerations of

volume and utilization should be balanced with other factors, such as scheduling and convenience, especially where operating costs are not significantly affected.

10. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

UMMS Comment

The Commission should provide more opportunity for public comment, including opportunities for stakeholders to address Commissioners directly. For example, the Commission should provide the opportunity for stakeholders to address Commissioners directly at meetings when new regulations are being considered for adoption. Currently, stakeholders may only make comments on regulatory changes during drafting process, and are not permitted to directly address the Commission at the public meeting.

In addition, if the Commission determines that it is appropriate to modernize the CON program in response to this comment process, the Commission should continue to provide opportunities for stakeholders to comment on the scope and nature of proposed changes throughout each step of the process.

General Review
Criteria for all Project Reviews

COMAR 10.24.01.08G{3}(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

11. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

UMMS Comment

Some of the general criteria are duplicative of the regulatory oversight of other agencies. As addressed in response to other questions, the HSCRC has specific expertise and broader regulatory control and enforcement capability over hospital spending than does the Commission. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 14, 17, and 24.)

As a result, UMMS recommends the removal of general criteria (2) Availability of More Cost-Effective Alternatives, and (3) Viability. The concerns that these standards address

are already appropriately met through the HSCRC's oversight. UMMS recommends maintaining the general criteria (1) Need, (4) Impact, and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded CON. This will require regulatory and legislative changes.

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

12. If you believe that CON regulation of hospital capital projects should be eliminated, what, if any, regulatory framework should govern hospital capital projects?

UMMS Comment

As addressed in response to other questions, the current All-Payer Model and HSCRC's oversight and control of hospital budgets provides sufficient governance of hospital capital spending, and the OHCQ and The Joint Commission provide appropriate regulatory oversight of quality and patient safety issues. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 4, 14, 17, and 24.)

13. What modifications would be needed in HSCRC's authority, if any, if the General Assembly eliminated CON regulation of hospital capital projects?

UMMS Comment

Deregulation of hospital capital projects will not require changes to the HSCRC's authority. As described in UMMS' initial comment, the HSCRC has sufficient authority to control hospital capital projects because hospitals must seek, and justify, rate changes in order to fund capital expenditures.

A minor legislative change would be needed to remove the reference to a CON in the definition of outpatient services provided in an FMF, Md. Code, Health General, § 19-201(d)(1)(iv).

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of hospital licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that certain hospital facilities and services are well-utilized and providing an acceptable level of care quality, with appropriate sanctions to address under- utilization or poor quality of care? Are there ways (other than those touched on in earlier questions) in which the regulation of hospital charges could be adapted as a substitute for CON regulation?

UMMS Comment

As addressed throughout these comments, the HSCRC and the OHCQ oversight that exists today adequately assures appropriate utilization and quality of hospital facilities and services. Specifically, the HSCRC's global budget revenue model carefully monitors utilization of hospital services and adjusts hospital budgets based on such utilization. Further regulation is not necessary.

Quality is an important consideration for every hospital. The OHCQ and The Joint Commission monitor hospital quality. Certain specialized hospital services also adhere to national guidelines. The Commission's lack of enforcement following first-use approval and the duplication of Commission and OHCQ review of quality issues make it preferable for quality issues to be within the exclusive control of the Maryland Department of Health.

The Impact of CON Regulation on Hospital Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing hospitals and new market entrants? If so, please provide detailed recommendations.

UMMS Comment

Maryland hospitals are well positioned under the All-Payer Model and GBR to innovate in service delivery. In light of that model and the HSCRC's oversight, the current CON process can impede hospital planning without a commensurate benefit. As addressed more fully in response to question 4, UMMS recommends deregulating a number of hospital projects that currently require CON.

16. Should Maryland shift its regulatory focus to regulation of hospital and health systems merger and consolidation activity to preserve and strengthen competition for hospital services?

UMMS Comment

Merger and consolidation activity in Maryland has not weakened competition for hospital services. Such consolidation has in fact proven to be an effective way for hospitals to decrease spending while maintaining access to critical services. In some cases, such as the recent affiliation of the former Dimensions Healthcare System within UMMS, merger and consolidation can result in bringing greater efficiency to the health care delivery system. Federal and state antitrust regulation also acts as an appropriate mechanism to promote competition.

Scope of CON Regulation

17. Should the scope of hospital CON regulation be more closely aligned with the impact of hospital projects on charges?

UMMS Comment

UMMS advocates against the adopting the measures suggested below. These questions recognize that under the regulatory landscape that exists in Maryland today, hospital planning is closely tied to each hospital's rates and GBR agreement. As discussed throughout these comments, there is regulatory duplication among the Commission and the HSCRC. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 14, and 17). The HSCRC appropriately interacts with hospitals to make adjustments to a hospital's GBR for appropriate hospital spending. The Commission should not consider adding regulation that duplicates the HSCRC's oversight, but instead should focus on removing existing duplicative oversight and focus on health care planning that is not effectively regulated by the HSCRC. The measures suggested in the questions below would add greater cost and uncertainty to health care planning without a commensurate benefit.

A. Should the use of a capital expenditure threshold in hospital CON regulation be eliminated? For example, should hospital capital projects or certain types of hospital project only require a CON if the hospital seeks an increase in its global budget to cover project-related capital cost (depreciation, interest, and amortization) increases? Alternatively, should CON regulation be based on the overall impact of projects on hospital revenues (related to coverage of both capital and operating expenses, which could increase substantially even for low cost projects if new services are being introduced?)

B. Should Maryland's system of hospital rate regulation include capital spending growth targets or capacity growth targets that shape the scope of CON regulation? If so, how would this work? For example, should CON regulation be redesigned to move away from single project review(s) for a multiple hospital system to a broader process of reviewing systems resource development needs and priorities? ~~Such a process~~

C. [Such a process] [c]ould resemble a periodic budget planning process with approval of a capital spending plan that incorporates a set of capital projects for a given budget period.

18. Should MHCC be given more flexibility in choosing which hospital projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information

related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the hospital to undergo ·CON review.

UMMS Comment

UMMS does not advocate the process described in this question. CON review should be a predictable process based on clear standards. The imposition of a flexible approach to whether a CON review is required may cause unpredictability and could potentially impose inconsistent burdens on different hospitals seeking to add the same service. Such a process could also have the unintended consequence of prolonging certain reviews – applicants could be required to provide a significant amount of information just to reach a determination as to whether staff will recommend CON review, followed by a potential full review. This initial step could be complicated by interested parties, yet excluding them from the first step would seem inappropriate.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

UMMS Comment

UMMS advocates a significant reduction in the scope of hospital projects that require CON review. If this deregulation is not accomplished, UMMS recommends, in the alternative, that that the Commission consider an expedited review process for projects for which UMMS recommends deregulation that instead continue to require CON review. For example, if the capital expenditures over the threshold are not deregulated, the Commission should consider an expedited review process for such projects.

New Jersey, for example, mandates an expedited review process that requires a decision to be rendered no later than 90 days after an eligible application has been accepted. *See* N.J.A.C §8-33, Chapter 5. While New Jersey's express categories of projects eligible for expedited review are narrower than UMMS would recommend as an alternative to complete deregulation, the process itself may be an appropriate model to consider. In addition to the projects expressly identified for expedited review, the applicable regulation allows use of the expedited review process "when the project has minimal impact on the health care system as a whole." N.J.A.C. 8:33-5.1(b).

The Commission should also consider an expedited review process for any CON that does not involve interested parties.

The Project Review Process

20. Are there specific steps that can be eliminated?

UMMS Comment

The current procedural steps involved in review of a CON project are appropriate. The process would benefit, however, from clear rules regarding the timing and scope of each step in the process. As described more fully in response to Question 5, hospitals are unable to determine how long the CON process will take with any degree of certainty, which is a significant impediment to the planning process. While clear rules regarding timing would be helpful for each procedural steps, UMMS recommends two in particular.

First, the process for the Commission staff's completeness review should be subject to timing and procedural limitations. The current completeness review often involves several rounds of completeness questions from Commission staff. Sometimes questions asked in later rounds do not concern new information provided in an applicant's responses to completeness questions, but material from the application itself available at the time of the first round of questions. This process sometimes causes unnecessary delay.

UMMS recommends that completeness review be limited to only one round of questions from Commission staff, with additional rounds permitted only to the extent the applicant failed to respond adequately to the initial questions or to the extent that any new completeness questions address new material and could not have been raised previously. UMMS also encourages the Commission to limit the scope of staff review such that additional information may be requested only if it is material to determining whether an applicant complies with a review standard or criteria. UMMS further recommends that the Commission promulgate a rule that states a prescribed period of time after an applicant's response to completeness questions within which the Commission must either submit any follow-up completeness questions that respond directly to new material provided, or confirm that the application is complete and docket it.

Second, UMMS recommends that there be clear rules governing when the Commission will seek comment from the HSCRC. In recent reviews, such comment is often sought near the end of a review. This may cause delay, especially where the Commission determines a modification or additional information is necessary based on the HSCRC's comment. UMMS recommends that the Commission seek input from the HSCRC as soon as the application is docketed, similar to the timing for interested party comments.

21. Should post-CON approval processes be changed to accommodate easier project modifications?

UMMS Comment

UMMS recommends that the Commission consider ways to allow for greater flexibility in both the changes permitted post-CON approval and the process for receiving approval. For example, the scope of impermissible changes should be reconsidered to allow for most changes where an applicant can demonstrate good cause. The Commission should also consider a speedy, staff-driven review process for certain changes, such as an increase in capital costs up to a certain percentage, subject to the right of CON holders to appeal to the full Commission.

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered.

UMMS Comment

As described in response to Question 4, UMMS recommends significant deregulation of projects that currently require CON review. (*See also* UMMS response to Question 19.) If the Commission and the General Assembly do not fully deregulate each of the projects described in UMMS' response, UMMS would support in the alternative a more abbreviated form of review for those projects.

23. Would greater use of technology including the submission of automated and form-based applications improve the application submission process?

UMMS Comment

Use of available technology would improve the CON application process.

For example, the process could be made more efficient and transparent through the electronic submission of applications and electronic docketing of other filings. Several states use electronic filing for docket management of their CON matters.[3] Federal

[3] There is a range in how states use electronic filing, from optional to mandatory, use for only for certain steps (*e.g.*, electronic filing of application following paper submission of letter of intent), or use for only certain types of reviews (*e.g.*, paper filings required for comparative reviews). *See, e.g.*, Alabama State Health Planning & Development Agency, SHPDA Online Filing System, "intended to allow applicants and interested parties to file documents related to CON filings," http://www.shpda.state.al.us/OnlineFiling.aspx (Jan. 22, 2018); Michigan Department of Health e-Serve Application ("allows users to submit applications and view CON information….[via an] online application housed and maintained through the State of

courts have used an electronic filing system for more than 15 years. Under such a system, applicants, interested parties, and the MHCC would submit filings by uploading them through an online docketing interface. The materials would be available for public inspection immediately.

Duplication of Responsibilities by MHCC, HSCRC, and the MOH

24. Are there areas of regulatory duplication in the hospital capital funding process that can be streamlined between HSCRC and MHCC, and between MHCC and the MDH?

UMMS Comment

As discussed throughout these comments, there is regulatory duplication among the Commission, HSCRC and the Maryland Department of Health. (*See* cover letter enclosing comments, opening comment, and comments in response to Questions 11, 14, and 17).

In particular, under the All-Payer Model and likely future agreements between the State of Maryland and the Centers for Medicare & Medicaid Services, HSCRC regulation and processes impose appropriate checks on hospital capital spending without the need for the CON process to require additional review of projects based on a capital expenditure threshold. Moreover, in light of the HSCRC's regulatory authority over hospital revenue and expenditures, there is no need for the CON process to include duplicative analyses to assess the financial feasibility, viability, or cost effectiveness of any proposed CON project.

25. Are there other areas of duplication among the three agencies that could benefit from streamlining?

UMMS Comment

The OHCQ's authority over licensure and other quality and patient safety issues renders CON standards that assess those issues duplicative and unnecessary. (*See also* cover letter enclosing comments, and comments in response to Question 14.)

Michigan MILogin System," available at http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-165238--,00.html (Jan 22, 2018); and New York State Electronic Certificate of Need (NYSE-CON), "a web-based, electronic application system designed to streamline the processing of applications, while improving communication and transparency," available at https://www.health.ny.gov/facilities/cons/nysecon/ (Jan 22, 2018).