Maryland
Hospital Association

January 22, 2018

Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Mr. Parker:

On behalf of its 64 member hospitals and health systems, the Maryland Hospital Association appreciates the opportunity to respond to the Maryland Health Care Commission's (MHCC) request for comments on Maryland's Certificate of Need (CON) program. Our response includes several key overarching principles related to Maryland's current All-Payer Model and future Enhanced Total Cost of Care Model (collectively, the model), as well as direct answers to the questions posed in the MHCC's Comment Guidance questionnaire.

Background and All-Payer Model Performance
Since the beginning of Maryland's All-Payer Model in January 2014, Maryland's hospitals have outperformed the model's per capita spending targets. Statewide, hospital spending per capita is growing more slowly than the nation, while Maryland's hospitals continue to maintain a robust range of services that all Marylanders can access. Across the country, hundreds of rural hospitals are at risk of closing, while other hospitals require greater state and local subsidies to ensure access to health care for local communities.

Because hospitals are responsible for the total cost of health care statewide, the commission should recognize the unique position of Maryland's hospitals when revising CON statutes and regulations. As we provide feedback on Certificate of Need, Maryland's unique rate setting system and our All-Payer Model performance remain at the forefront of our positions.

Key Principles
There are key expectations that guide hospital positions on CON, the State Health Plan for Facilities and Services (State Health Plan) and related MHCC regulations. These include:

- Maryland will continue to operate under its unique waiver from Medicare's payment systems, transitioning from the current All-Payer Model to the Enhanced Total Cost of Care Model beginning in January 2019
- By 2023, Maryland must guarantee $300 million in annual savings, for both hospital and non-hospital services, through slower growth in total Medicare spending *per beneficiary* than the nation

- The Maryland Health Services Cost Review Commission (HSCRC) will continue to set hospital rates
- Other than normal Medicaid payment schedules, Maryland will not set rates for non-hospital health care providers; should the Centers for Medicare & Medicaid Services (CMS) grant Maryland the authority to apply a Medicare Performance Adjustment (MPA) to differentiate non-hospital payments, implementation for non-hospital providers would be voluntary
- Though delivery system incentives may influence provider behavior, only hospitals, through the HSCRC's authority, are being held responsible and accountable to deliver annual Medicare savings

Maryland's All-Payer Model and Enhanced Total Cost of Care Model
Maryland's hospitals strongly support Certificate of Need under both models. Securing the Enhanced Total Cost of Care Model is a priority for Maryland's regulators and elected officials, and is fully supported by Maryland's hospitals. The models provide unparalleled access to health care services and prevent the cost shifting among payers that occurs in other states.

Both Medicare spending growth per beneficiary and all-payer spending growth per capita, for all services, are bound by the models. The historical waiver (prior to January 2014) only required that Maryland's inpatient Medicare prices grow slower than the nation. The enhanced model that will begin in January 2019 limits *total Medicare* spending growth *per beneficiary*, including price and volume, for all health care services.

Hospital global budgets provide powerful incentives to reduce unnecessary and avoidable use, but this incentive only applies directly to hospitals. Hospitals can indirectly affect non-hospital service use through partnerships and alignment incentives. However, non-hospital service providers are not subject to rate setting or global budgets. **Unlike with Maryland's hospitals, non-hospital revenues grow when service use and volume increase**. Therefore, any unchecked volume growth increases Medicare spending, directly driving up the total spending per Maryland Medicare beneficiary.

The HSCRC can adjust hospital rates to make up for this increase in order to comply with the overall spending limit. Certificate of Need is one of the few tools to regulate the supply of health care services. Under Maryland's current All-Payer Model, significantly eroding or removing Certificate of Need barriers would not be appropriate. Maryland's hospitals, like all stakeholders, are willing to modernize CON and the State Health Plan, but the core principles of CON should remain in place.

MHCC plays an important role, issuing policies through the State Health Plan for Facilities and Services (State Health Plan). This policy role ensures Marylanders have access to quality, efficient health care. Determining the complement of available services throughout the state is the foundation of health care delivery, aligning with model incentives to provide the right care, at the right time, in the right setting, for every patient.

Comment Guidance Responses
Responses from the hospital field are attached to this letter. In several instances, the responses are based on our understanding of the question, but additional clarification may be needed. In those cases, we explicitly noted how we read the question.

In addition to this feedback, MHA's Certificate of Need and State Health Plan hospital work group is concurrently addressing these important issues. Further responses to the commission's questions are expected to be an outcome of the work group's review of these issues. For example, question 8 asks about the strengths and weaknesses of State Health Plan regulations. MHA's work group will first assess the overall purpose of the State Health Plan, and then review each chapter to suggest specific modifications.

Our initial responses are focused on hospitals and hospital services. However, through MHA's work group review process, we will provide feedback to the commission on State Health Plan chapters and other policies that affect non-hospital services. In some responses, we have provided general recommendations. MHA's work group will likely respond with specific, detailed recommendations as we complete our issue review.

We appreciate the commission's detailed and thorough approach to Certificate of Need review and Maryland's hospitals look forward to continuing to provide the commission with feedback on current considerations, potential changes and future impacts.

Thank you for your consideration.

Should you have any questions, please call me at 410-540-5060.

Sincerely,

Brett McCone
Vice President

cc: Robert Emmet Moffit, PhD., Chairman, MHCC
Ben Steffen, Executive Director, MHCC
Kevin McDonald, Chief, Certificate of Need, MHCC
Donna Kinzer, Executive Director, MHCC

Enclosure

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 work group.

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.

The Maryland Hospital Association's (MHA) 2015 Certificate of Need Task Force, consisting of hospital CEOs and senior health planning and finance executives, concluded that a CON process is needed to determine the most efficient use of limited resources. The main reasons for this conclusion are that Maryland's hospitals are bound by the All-Payer Model and that Maryland's hospital payments are set by the Health Services Cost Review Commission (HSCRC).

As reflected in our cover letter, Maryland's hospitals strongly support CON as both appropriate and necessary under Maryland's unique All-Payer Model and the upcoming Enhanced Total Cost of Care Model (collectively, the model). Maryland's hospitals are the only health care providers accountable for achieving the financial and quality targets reflected in the agreement with the Centers for Medicare & Medicaid Services (CMS).

Though hospitals support CON, the task force recommended that MHA convene a second work group to assess appropriate statutes and regulations, and recommend specific revisions if needed. Certain aspects of CON require modernization. MHA's Certificate of Need and State Health Plan Work Group held its first meeting on November 8 to begin this work.

Because hospitals are responsible for the total cost of health care statewide, the commission should recognize the unique position of Maryland's hospitals when revising CON statutes

and regulations. MHA's work group is reviewing CON, the State Health Plan and other regulations, and will bring specific, consensus recommendations to the commission as the group finishes its issue review. Many recommendations will not be complete by the January 26, 2018, deadline, and some may not be complete until the middle of calendar year 2018.

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?

   In the existing CON environment, there is abundant, healthy hospital competition. Competition is just as visible as before the All-Payer Model and it exists with CON rules in place. In addition to hospitals competing with each other, hospitals compete with other providers for certain services, including outpatient surgery, diagnostic imaging, infusion, etc.

   At the same time, the model provides incentives for hospital collaboration in an attempt to reduce hospital costs, particularly for the chronically ill population. Hospital and regional partnerships have been formed to manage the health of the population, and large hospital systems drive collaboration among their subsidiaries. ***Since the beginning of the model, Medicare hospital spending per beneficiary has grown more slowly than all other health care market segments.*** *This trend has occurred without modifying CON rules.*

   Across the state, hospitals constantly compete with one another for services. Hospital competition is good. It can drive service innovation and efficiency, particularly since hospitals are accountable for Maryland's performance. Adding more hospitals or hospital services will not necessarily lower costs or improve quality, especially in areas with excess hospital capacity. Where there is excess capacity, regulatory efforts should incentivize appropriate access to care, while encouraging the repurposing or conversion of resources to address other health needs.

2. Does CON regulation impose substantial barriers to market entry for new hospitals or new hospital services?

   (We read "new hospitals" as a newly constructed hospital that did not previously exist, and hospital services as hospital services currently subject to CON.)

   Yes, CON imposes a barrier to unneeded market entry. We believe this barrier to market entry, either for a new hospital or a new hospital service, is appropriate. CON is appropriate to ensure access to services, and the quality of those services at the lowest possible cost.

A core tenet of CON is to prevent duplication of services, particularly for a new hospital. Certain specialized services – transplants, cardiac surgery, etc. – require CON because there are critical levels of volume needed to achieve quality standards. CON serves as an appropriate barrier to ensure a minimum level of volume is achieved. CON regulations should be based on what services are needed using an objective methodology.

Importantly, the All-Payer Model affects the demand for health care services, which in turn, affects the need for services. The model requires the CON barrier, and the CON barrier supports the desired outcome of the model to reduce total spending per capita. Assuming that HSCRC and hospital rate regulation remain, HSCRC will closely regulate capital funding in hospital rates to ensure that Maryland meets the model's targets.

Hospital and health system operating margins, and the current market environment – from competition for physician resources to the incentives to collaborate – provide additional, inherent barriers to prevent the development of unnecessary services. These barriers naturally apply before an organization considers developing a new service that requires CON approval.

If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

As reflected in the answer to question 1, there is abundant hospital competition in the current environment, and the model's incentives encourage hospitals to collaborate.

The work group is reviewing CON, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its review. Preliminarily, hospitals suggest reviewing regulations that are no longer required because they were implemented prior to specialized care standards being established (e.g., perinatal standards may replace the need for neo-national certificate of need approval). Any changes should not undermine the core principles of CON. The approach to CON, gathering market and regulatory information that has evolved over the years, should be modernized.

There is strong need for adequate behavioral health services to address access and quality. Any regulation assessment should begin with behavioral health services, given the current market dynamics and the dated state health plan regulations.

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?

As reflected in our answer to question 1, there is abundant competition in the current environment, while the model's incentives also encourage hospitals to collaborate with each other. Further, Maryland's hospitals are some of the most innovative health care institutions in the United States. Maryland's All-Payer Model provides incentives for innovation designed to achieve the triple aim.

This question appears to be about how reimbursement encourages or discourages innovation. In certain cases, reimbursement hasn't caught up to innovation, but this is often a reality of the market. Certificate of Need neither stifles nor enhances innovation.

MHCC, HSCRC and the state need to think innovatively about how care can be provided more effectively in lower cost settings, delivered where people need the services. For example, the Freestanding Medical Facility statutory changes in 2016 were designed to make it easier to reduce capacity. In achieving this transformation, the perception is that state regulatory agencies should be much more responsive and flexible to achieve the intent. The statutes and policies have been changed, but the regulatory burden, either through process or interpretation, has not. More than just the commission, other state agencies are involved. This includes the Office of Health Care Quality and Maryland Institute for Emergency Medical Services Systems. MHCC, through statute or regulation, could play a leading role to shepherd innovation among all regulatory agencies.

The State Health Plan should be updated in accordance with the statute. This means more timely reviews of each chapter as innovation drives health care delivery system changes.

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=10.24.01.**

4. Should the scope of CON regulation be changed?

The general scope of CON is appropriate and reasonable. There are adjustments that can and should be made, but these adjustments do not fundamentally alter the CON program.

The work group is reviewing CON, the State Health Plan and other regulations, and will bring specific recommendations to the commission as the group finishes its issue review. See responses to question 2 and question 3 for initial reactions. If other regulatory systems are in place, the commission might consider removing certain regulatory requirements.

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

The commission should consider eliminating, or significantly raising, the capital spending threshold for projects that do not change the number of a hospital's beds

or expand covered hospital services. Additionally, MHCC might consider limiting the scope of services required under CON (e.g., the perinatal example in the response to question 2.)

As reflected in the cover letter, our principles state that Maryland's All-Payer Model will continue, so the need to align CON and model incentives is critical. Ultimately, review of CON may require rethinking HSCRC regulatory approaches. Historically, CON approval was the "key to unlock the door" to potential capital rate relief. If the capital threshold is raised or eliminated, this may change the view of CON requirements for rate relief.

Hospital boards are stewards of community resources, and are not going to invest in capital projects they cannot afford. In our answer to question 2, operating margins and the health care market are natural barriers to unchecked service development. The availability and concentration of scarce clinical resources is another inherent barrier to service development, no matter what the community desires.

The MHCC guidance contemplates deregulating services and creating new review classes as ideas to improve the CON application process. Reducing unnecessary approval steps and enforcing the decision timeline, coupled with clear rules and consistent interpretation of those rules, will streamline reviews without changing CON requirements.

Though not an MHCC issue, an alternative is to potentially allow hospitals to deregulate outpatient services on an expedited basis. Alternatives might include moving services to unregulated space, or allowing services to be deregulated in place, within a hospital. The latter raises several issues, but all options should be identified. Our work group is still discussing this.

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?

Our work group is discussing this, and how CON statutes and regulations should address this consideration against the backdrop of the model's constraints.

Without recommending additions to the scope of CON regulation, we remind the commission that there are a range of services provided at hospitals that are not covered by CON, or can be exempt from CON, if provided outside of the hospital. Diagnostic imaging, infusion, and ambulatory surgery contribute significantly to covering the fixed costs and semi-fixed costs required to operate hospitals. Outside of hospitals, when Medicare volume increases, total Medicare spending per beneficiary increases.

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?

   CON approval, unless contested, is supposed to be complete in 150 days. Maryland's hospitals identified potential areas for the commission to address:

   - *Before an application is even docketed, completeness questions can cause significant delays. We recommend that the commission limit MHCC staff to one round of completeness questions, and the completeness questions must be germane and essential to making a decision on the CON application.*
   - *From the hospital perspective, MHCC regulations governing charity and uncompensated care should be moved to the HSCRC's jurisdiction. This includes the timeline for determination of whether a patient is eligible for charity care. HSCRC governs hospital rates, including charity care and uncompensated care provisions. MHCC may continue to request this information from other providers to fulfill certain requirements for CON eligibility.*
   - *For hospital projects, financial feasibility and analysis should be the purview of HSCRC. This should eliminate the need to file two sets of financial projections – one to MHCC without inflation and one to HSCRC with inflation. Hospitals that assume a rate increase for financial feasibility will naturally require additional approval steps. They must concurrently file an HSCRC rate application requesting the rate increase reflected in the CON application.*
   - *Even with projects that include interested parties and/or involve comparative review, a delay in a single application step should not automatically delay deadlines throughout the whole project. Hospitals agree that if an applicant has delayed the process, then the applicant must recognize the consequences.*
   - *The submission forms can run in excess of 120 pages. The commission should review the submission forms and eliminate anything that is not required to determine CON approval.*
   - *For renovation-only projects that do not change the scope of hospital services, the commission should consider replacing the quantitative analysis with a simple narrative. Hospital margins and the hospital's board of directors should demonstrate adequate stewardship of resources.*
   - *Applicants should not have to submit pro-forma documentation if the documentation has already been filed with MHCC, the HSCRC or another state regulatory agency.*

   In general, the SHP must have clear and straightforward guidelines, and MHCC must follow those guidelines. The MHA work group plans to thoroughly review the general MHCC regulations and the SHP chapters. Recommendations from this review will aim to improve the application process by refining review steps.

The commission should also consider the number of CON subject-matter experts on staff. This number may need to increase, and/or the service experience complement may need to change (hospital, skilled nursing, etc.), to improve the process.

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

   No, the commission should not consider limiting interested parties on projects. The commission already has statutes and regulations in place to determine interested and "adversely affected" parties. Those seeking to be interested parties must demonstrate impact from the proposed project. This impact should be demonstrated with well-organized, data-driven analyses and not a presumption of impact. This might include parties that have services in the applicant's service area, or parties that may be impacted if the applicant is seeking specialized regional or statewide services. Even with interested parties, the approval process should not be delayed.

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated?

   This issue will be considered by the work group.

   The CON exemption review process is arduous, requiring significant time and effort before the commission grants an exemption. The main difference between a CON exemption request and CON approval is the allowance of interested parties. However, a CON exemption request requires much of the same information and many of the same review steps.

   The commission might simplify the requirements to grant CON exemptions. If the commission is concerned about quality of care, the licensure requirements could be reviewed and augmented.

   Should further consolidation of health care facilities be encouraged by maintaining exemption review for merged asset systems?

   The exemption for merged asset systems should continue. The model creates incentives for cooperation and collaboration among hospitals, health systems, and community organizations. We should not erect barriers that prevent hospitals from operating efficiently, including efficiencies realized when resources are appropriately combined. To reduce the cost of health care, hospitals and health systems need to operate as efficiently as possible, often through the use of umbrella/overhead departments required to manage the back-end functions of the organization. Merged asset systems create efficiencies through economies of scale, particularly around functions like patient accounting, information technology, etc.

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

   Project completion timelines should be reviewed, particularly reporting compliance after project approval. Currently, the post-approval quarterly reporting forms are very complicated, especially for a large project. The forms should be simple and should only collect information that was relevant to the project approval decision.

   Though largely an HSCRC issue, the commission might also consider an approved project's impact on spending per capita. After the project is approved and in service, for the primary service area, the commission could measure the service-specific spending per capita compared to a prior period.

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?

   The State Health Plan should begin with a clear purpose, accompanied by two to three key goals and objectives. The purpose and goals should align with the model because the state is collectively at risk to achieve the model's goals. In particular, the plans goals should take into account the model's influence on the demand for health care services, which in turn influences the "need" for services.

   The chief strength of these regulations is the idea that there should be "standard" criteria to determine the need for a project. However, incentives in the Maryland model directly affect the demand for services. State Health Plan criteria deal with providing an adequate supply of services to meet the demand.

   The regulations are static, and some haven't been updated in many years. The inpatient psychiatric services chapter has not been substantially updated in 20 years. Meanwhile, the state closed several state-owned psychiatric facilities. The State Health Plan needs to be updated, and flexible enough to account for changes in emerging technologies, like telehealth, as well as technologies that don't exist yet, but will shape future health care delivery.

   As reflected in our cover letter, MHA's work group plans to discuss the purpose and goals of the State Health Plan. The work group then plans a chapter-by-chapter review to suggest revisions and modifications. We expect this process to take place concurrently with the commission's work group.

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

   See response to question 8, in particular the last paragraph.

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.

    The State Health Plan should be more regularly reviewed and updated, in accordance with the current legal requirements. MHA's work group acknowledged that a SHP chapter review involves a significant time commitment. Given the commitment, the commission, with input from the public, should prioritize the SHP chapters that are ripe for review and revision.

    When State Health Plan chapters are revised, commission staff create a stakeholder work group to provide input and feedback. This feedback is then synthesized by commission staff into a series of recommendations, and a revised chapter is drafted. The commission will solicit informal, then formal public comments. These comments receive written responses from staff that are shared with commissioners. However, oral comments are not considered at the public meetings. When ripe for commission action on a chapter of the State Health Plan, the commission should welcome comments at a public meeting.

    At a minimum, at the end of this review process, when the commissioner-led work group releases its final recommendations for commission action, the full commission should allow presentations and comments before voting.

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?

    In general, the criteria are appropriate but need to be applied consistently to all CON applications, particularly the "need" criteria. The criteria should be reviewed to determine the model's influence on the demand for services. This influence may require revising the need criteria, particularly the formulas to determine inpatient beds.

The MHA work group is reviewing the State Health Plan. Recommendations will be shared with the commission when the process is complete. At a minimum, ***hospital requirements*** *to report charity/uncompensated care are not needed, or should fall under HSCRC jurisdiction.*

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?

    Maryland's hospitals strongly support the continuation of CON requirements. *CON is appropriately necessary to operate under Maryland's All-Payer Model. We are reviewing individual services to determine whether certain regulations are no longer required because other clinical or application standards have been established.*

    Absent another mechanism to hold non-hospital service providers accountable for achieving model targets, the commission must continue to regulate the supply of services.

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

    See the response to question 12.

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?

    Given the unique payment system in Maryland, CON is needed to determine the most efficient use of limited resources.

    From a financial perspective, the HSCRC serves as an important hospital regulatory body. HSCRC and the Maryland Department of Health are leading the negotiations to extend Maryland's All-Payer Model. HSCRC has imposed global budgets that create much different incentives to constrain avoidable and unnecessary health care service use. We do not propose that HSCRC set rates or otherwise regulate non-hospital providers, but we would remind the commission that hospitals are already heavily regulated.

Though hospitals support the overarching CON principles, other regulatory requirements might be leveraged to appropriately regulate other health care services. Licensing and/or certification requirements should be explored further.

Changes to regulatory mechanisms, particularly out of MHCC's scope, may require a reallocation of resources away from MHCC to other state agencies, with a corresponding reduction in MHCC user fees.

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.

See the response to question 3. CON is not an impediment to innovation. Changes in the hospital payment system have created incentives for Maryland's hospitals to serve as innovators. The hospital marketplace provides an appropriate balance of competition and collaboration. By adopting, supporting and extending the model, the state, through HSCRC, has given hospitals the implicit directive to collaborate and improve the health of the population. Global budgets are driving innovative alignments of hospitals, physicians and post-acute providers.

More timely updates of the SHP are needed as delivery system changes outpace the existing regulations. MHA's work group is reviewing CON, State Health Plan and other regulations to determine specific revisions.

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?

Absolutely not**. Maryland should not focus on regulating mergers and consolidation activity. This question suggests that mergers and acquisitions reduce hospital competition. **Maryland's hospitals strongly disagree with this implied assertion.

In fact, hospital mergers, consolidations and affiliations have strengthened health care service delivery in Maryland. There are several examples of the benefits of mergers and consolidations having eliminated fixed costs and generated system savings. Three examples are: the consolidation of hospital services in Alleghany County, the proposed conversion of small acute care hospitals in Easton and Havre de Grace to emergent and outpatient facilities, and eventual redevelopment of hospital facilities in Prince George's County that previously required significant public subsidies (University of Maryland Capital Region Health.)

The merged asset exemption allows for health systems to better allocate/align services and avoid unnecessary duplication. This should continue and be encouraged across all providers. There are also substantial quality benefits from hospital mergers due to the

standardization of clinical protocols and concentration of complex services at a limited number of hospitals.

Other regulatory bodies already provide adequate oversight of hospital mergers – the Federal Trade Commission, the Department of Justice and the antitrust division of the Attorney General's office.

Scope of CON Regulation

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

    No, there are sufficient incentives under the All-Payer model to control hospital charges. The model limits all-payer per capita growth and Medicare payment per beneficiary growth. Any rate increase to cover capital expenditures will affect these growth rates. Therefore, hospitals must reduce avoidable and unnecessary service use to generate additional savings, or the HSCRC must regulate hospital payment rates to maintain compliance with the model.

    Non-hospital providers have the ability to grow volume to pay for capital and operating expansions. Unlike hospitals, these providers are not subject to global budgets, and therefore revenues will increase as volumes increase.

    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?)

       Please see the response to question 4A.

       For projects that do not add hospital beds or change the hospital service portfolio, the commission should consider eliminating, or significantly raising, the capital threshold.

       Unless HSCRC grants a hospital rate increase, no additional revenue is added to the system for approved hospital projects. The hospital provider, or parent health system, is at risk for having the resources to cover capital expenses. Operating revenue may increase from market shift, or the hospital has the ability to file a rate increase application. ***However, Maryland's all-payer per capita growth and Medicare spending per beneficiary growth are ultimately capped by the model and HSCRC regulates hospital revenue to ensure compliance.***

A different approach might be to estimate the impact of the project on total cost of care growth, particularly for non-hospital services. This could be done when evaluating a CON application, or by determining that services should be added or removed from the scope of CON regulations.

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 could 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.

We do not support this approach. The hospital market encourages a balance of competition and collaboration. The commission should review each project on its individual merits and should not predetermine capital projects for a given period. This would stifle innovation and the ability of the market to determine the most efficient use of capital, conditions that exist under the current CON regulatory umbrella. We do not support deregulation of CON, and we do not support the commission usurping health system management and planning functions.

Maryland's rate regulation system should provide hospitals adequate capital funding. When the rate setting system was developed, funds were not placed in rates for replacement or renovation of aging facilities. Rather, HSCRC would review and approve hospital rate increases to cover the cost of capital at the time of replacement. Under a fixed revenue system, HSCRC might consider revising the historic Capital Facilities Allowance that provided hospitals with a benchmark for capital funding. MHA's work group may explore this issue further.

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.

No, the MHCC should not be given more flexibility in choosing which projects require approval. This would likely result in greater uncertainty and the potential for arbitrary decisions. The commission should adopt policy principles and clear, unambiguous regulations to guide decision making. Decisions should be applied consistently. If the application process is too complicated, simplify the regulations that govern the process and eliminate unnecessary steps that will not affect decisions by the commission. The policy principles should be reviewed at regular intervals with respect to Maryland's

performance under the forthcoming Enhanced Total Cost of Care Model, and the regulations, including chapters of the SHP, should be updated on a regular basis. The policy principles may reference incentives to expand or contract types of service providers, steered by having the flexibility to determine which providers or projects require CON approval.

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

    The previous MHA CON Task Force discussed a "fast track" approach for projects with no interested parties and a documented need in the State Health Plan. Other possibilities include no assumption of hospital rate increases or project that demonstrate significant cost savings.

The Project Review Process

20. Are there specific steps that can be eliminated?

    Completeness questions should be limited to one round, and they should be limited to only those issues that are essential to a commission decision.

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

    Yes, particularly for projects without new beds or services.

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.

    See the response to question 19. Additionally, if the State Health Plan is updated on a regular basis, it will improve the process by eliminating certain requirements. Changing the state health plan should create room to expedite reviews for small delivery changes.

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

    Possibly, but if the form continues to exceed 120 pages, it will still be arduous. The commission should explore the potential to submit auto-generated forms for post CON follow up. The commission should review what is currently required in a CON application to determine if the information is critical to making a decision, or, whether the information is already publicly available.

    Questions 20 through 23 will continue to be discussed by the MHA work group.

*In general, **the commission should identify steps that add little or no value to the CON decision-making process and remove those steps.** Several areas should be considered, including the charity care policy, cost per square foot benchmarks, etc. The commission should investigate whether an incentive that created the CON requirement is still valid, or whether the incentive been superseded by other regulatory actions, innovation, and/or market forces. **Commissioners and the legislature should not hesitate to eliminate steps that are no longer necessary, but have not changed because there has been no real incentive to change.** We agree with commission staff that "rules matter." It's time to review the rules and eliminate those that are unneeded.*

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

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?

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

MHA's work group will discuss these questions and provide specific responses to the stakeholder work group.

Questions 24 and 25 are broader than CON and state health plan review. Responding to these questions provides MHA's work group the opportunity to comment more generally on MHCC and its mission. The MHCC has been an advocate for innovation, helping create pilot programs to improve access and reduce costs. The desire to modernize CON may require a broad look at the commission, including its "core missions" like CON, and the appropriate resources to complete these core missions.

In the response to question 11, the general standard for charity care for hospitals should be eliminated or moved to the HSCRC's authority.

Thank you for your responses. Remember that it will be helpful if you provide a brief explanation of the basis for your position(s) and /or recommendation(s) in each area of inquiry.