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.]

X CON regulation of hospital capital projects should be reformed.

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

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?

   Carroll Hospital feels the CON process has served the state well in terms of ensuring quality and appropriate access to care and should continue to do so. Additionally, Carroll Hospital feels that the current infrastructure of hospitals and health systems in Maryland provide sufficient competition and scope of services, both general and specialty. While we view competition as essential and a driver of innovation and performance, under Maryland's payor system and the new CMS regulation that holds the state of Maryland and Maryland hospitals accountable for the total cost of care, the introduction of more service capacity that is likely to occur in the absence of a strong CON process, would not positively impact Maryland's ability to reach cost saving targets.

Carroll Hospital also believes patients in Maryland are well served by the high standards set forth by federal, licensing, regulatory and accrediting bodies including CMS and the Joint Commission as well as the numerous quality measures that are closely monitored and publically reported. Additionally, as they are challenged by increasingly stringent standards for improving the quality and experience of care and improving the overall health of populations, while reducing per capita costs of health care, hospitals continue to drive innovation that benefit their patients.

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?

   The schedule for submitting CONs is limiting. (More comments on these issues in the questions that follow.)

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?

   While Carroll Hospital Health feels the CON process is essential and should stay in effect for services, especially those for open heart, in some cases, the CON regulation can stifle innovation in improving quality and the delivery of hospital services. In most cases, hospitals will not receive a rate adjustment for projects that improve the physical plant of a facility. We feel in these specific cases, much of the existing CON process unnecessarily prolongs projects most often designed to improve patient care, quality and safety. As hospital across the state look for "cost-effective approaches to meeting identified needs" LifeBridge Health feels that in some circumstances the CON process could be modified. In those isolated cases (covered in more detail below), licensing bodies can continue to adequately monitor quality.

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

Carroll feels the CON process is a good one and should stay intact. Based on the premise stated above, however, LifeBridge Health would recommend deregulating or modifying the regulations for the following specific cases:

1) Renovation and replacement (new builds) projects that do not increase the physical bed count (over 10%), even if the cost exceeds the threshold established by the Maryland statute.

2) If you are going to keep the capital expenditure threshold, increase it to $16M.

3) For nursing homes that meet certain quality metrics (tbd), the addition of waiver beds should be modified to allow an increase of 20 or 20%; and the timeframe for adding those beds should be increased to every year, instead of every two years, again based on the facility meeting certain quality metrics.

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?

LifeBridge Health feels there should be a level playing field for hospitals and those offering ambulatory surgery services in free-standing facilities. If hospitals are required to submit a CON to increase surgical capacity, then free-standing ASCs should have to do the same, regardless of their size.

<u>The Project Review Process</u>

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

- **The schedule for CON review is somewhat restrictive. If you miss an application submission date, you have to wait at least six months to file a CON.**

- **Completeness questions traditionally add a significant amount of time to the process and involve substantial amount of time and resources by hospitals. The questions are most often unnecessarily detailed and often request an excessive volume of supporting documentation. That includes brochures, training manuals, etc. For example, when our most recent CON was filed, the Commission requested the entire volunteer training manual; promotional brochures and registration paperwork. That resulted in nearly 300 additional pages that needed to be copied, scanned and submitted. While we understand there will be additional questions or clarifications required, we do feel the Commission could ease the process and burden on hospitals by accepting a reference made to what's available and how it's used.**

Additionally, facilities have 10 business days to respond to the completeness questions, but while the Commission has similar time requirements for docketing; assigning a reviewer to complete CONs; or approving/reaching a decision on completed CONs, you do not always follow those timeline requirements. This significantly delays the progress of projects and has the potential to adversely impact capital costs, permitting, contracting, hiring and the health of a community. The Commission should have to be held to time requirements for processing CONs, for instance, no longer than 90 days. Or, if they do, the organization has some recourse to move forward with their project.

As an example, it has been more than a year since Carroll Hospital filed a CON for providing home-based hospice care in Baltimore City. It was presented in December 2016, docketed in July 2017 and a reviewer still has not been assigned to that application. While we understand that the Commission has experienced turnover, by any standards, for this and other important projects, more than 12 months is entirely too long to wait for a review and decision by the Commission.

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

   Yes. We feel interested party comments should be limited to hospitals/providers physically located within a certain radius or your jurisdiction who provide the same care and should only be considered if the project has implications that adversely impact patient care or unreasonably limit patient choice.

7. 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?

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

   We would like the Commission to consider eliminating the requirement of submitting quarterly updates on the progress of construction projects. We feel that the construction schedule should suffice and that perhaps hospitals should only have to notify the Commission if the project completion date is prolonged by 60 or more days.

<u>The State Health Plan for Facilities and Services</u>

9. 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?

10. 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.

11. 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.

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.

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

    Carroll feels that much of this information is excessive and in some cases unknown and immaterial:

    Viability: Tables and financial information could be significantly pared down, especially the duplicative requests. Perhaps a brief business plan (1-2 pages) could be used.

    Impact on Others: This often is speculation by hospitals. Carroll Hospital questions what value this brings and if it should be considered at all in the CON process. As previously mentioned we feel competition is good and hospitals carefully consider every investment made, capital or otherwise, so it should not be the applying hospital's responsibility to explain how its project will impact others. Facilities should consider that there is competition for services and they should be able to freely invest in projects that most benefit patients and address safety and unmet needs, within the guidelines of the MHCC.

    Terms and Conditions of Previous CONs: This section in particular is one we feel could be removed altogether from the application. We feel the Commission should already know if the hospital has been compliant with its previous applications. Also, to ask for 17 years' worth of information seems disproportionate. Maybe the question could request hospitals to affirm

that it has been compliant with following CON guidelines and have submitted CONs appropriately. Or, significantly shorten the timeframe for which you're requesting information to no more than 24-36 months.

CHANGES/SOLUTIONS

Alternatives to CON Regulation for Capital Project

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

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

15. 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?

The Impact of CON Regulation on Hospital Competition and Innovation

16. 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.

17. 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?

Scope of CON Regulation

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

No. LifeBridge Health and most hospitals and health systems have stringent budgeting processes already in place. We do not feel that the budgeting process should be expanded to include the Maryland Health Care Commission.

19. 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.

Carroll Hospital would prefer a more definitive approach any changes to the approval process, meaning specific changes should be made to the guidelines for what projects require a CON. We do feel strongly that hospitals and the MHCC should continue to have the flexibility in considering unique situations on a case by case basis via the existing determination process.

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

Yes. As outlined earlier, Carroll would fully support an abbreviated process for certain projects that includes a brief description of purpose, cost, funding, timeline and operational impact.

The Project Review Process

21. Are there specific steps that can be eliminated?
Yes, as partially outlined previously the Commission should consider:

- **Eliminating the LOI requirement.**
- **Revising or eliminating the schedule for CON submission.**
- **Limiting "Completeness Questions"**
- **Eliminating the requirement to deliver five hard copies of the application and ALL attachments to the Commission. Perhaps the Commission could go paperless and require only one hard copy.**
- **Eliminating the Quarterly Status Reporting requirement for open CON projects.**
- **Eliminating the requirement of hospitals having to send acknowledgment of receipt of the Commission's First Use Approval.**

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

    The modification process could be simplified and the thresholds modified so that fewer projects need to go through the official modification process. The Commission could consider changing the threshold to a fixed percentage of over the original total capital costs. Five percent may be a good target.

23. 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.

    Yes. See previous comments.

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

    Yes, see previous comments. Questions 22.

<u>Duplication of Responsibilities by MHCC, HSCRC, and the MDH</u>

25. 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?

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

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.