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Paul Parker
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Maryland Health Care Commission
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RE: MHCC CON Study, 2017-2018

Dear Paul:

In response to the request dated November 17, 2017 for input on the efforts of the Maryland Health Care Commission to "achieve the goals of the Triple Aim and to bring health care spending under a total cost of care model," Anne Arundel Medical Center is pleased to provide these comments on the 25 questions you posed. Also, please be aware that our organization is an active participant in the Maryland Hospital Association's Certificate of Need (CON) and State Health Plan Work group. As such, we are largely in support of the position paper and responses they are providing on behalf of Maryland's hospitals and health systems.

**Need for CON Regulation**

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

a. 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).

b. CON regulation of hospital capital projects should be reformed.

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

***b. The best option is the one that allows CON regulation to be aligned with the new payment model, Global Budget Revenue (GBR), that was implemented in 2014 and the next version, which will be Total Cost of Care (TCOC) in 2019. What would be valued is a CON process that preserves the principles of ensuring adequate access to high quality, low cost hospitals and health care related services that are currently regulated. Another important design principle is flexibility with incentives for innovation.***

*Projects that are being reviewed only because the capital threshold has been exceeded (i.e. the current the capital threshold of $11M) should qualify for a modified, more efficient process.*

**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?

***Hospitals are already intensely competing, albeit more so in some markets than others. The competition is not limited to other hospitals. Health systems can operate several or all pieces of the continuum of care and therefore, compete with post-acute and non-acute providers. Standalone hospitals compete with other providers. In some instances, providers of unregulated services such as urgent care centers, freestanding radiation centers and freestanding surgery centers, create an uneven playing field for hospitals as the barriers to entry are lower and other regulations and restrictions are not as stringent. Competition to provide high quality, low cost and accessible health care can benefit Maryland's communities. Likewise, encouraging innovation by incenting vertical and clinical integration via the regulatory channels of CON, exemption from CON and oversight is a good idea. As a result of competition, an environment where a health system is growing and developing in a way that aligns with the attributes of a TCOC environment versus being stifled by regulatory barrier, should be encouraged and supported.***

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?

***Yes, CON regulation imposes substantial barriers. The focus and priority should be on having sufficient barriers to prevent TCOC from increasing due to new, for-profit entrants in the unregulated environment. Competition usually chases high margins. Given the tight constraints on hospital margins, and the sufficient (if not excess) capacity in some markets, we are unlikely to see new hospitals. However, sometimes these barriers also present formidable challenges to providing accessible, needed health care, as is the case in bringing more inpatient mental health care to a region. There are some critical needs as identified by the local community health needs assessments (CHNA). Some of these needs can only be met by adding services. If the CON regulatory process poses a barrier to adding these services versus creating access, regulation of these services should be evaluated. An example of one service would be mental health services. If a CHNA has identified mental health as a top priority, the MHCC should consider deregulating the service from CON. Need has been proven and the community deserves access.***

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?

***The CON process is too rigid, too cumbersome and too slow. Hospitals are not afraid of innovation. Indeed, they continually investigate ways to be better, safer, more efficient and less costly. Regulation and innovation should not be mutually exclusive.***

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?

***There should be reconsideration of the capital threshold requirement for a CON. Hospitals will not undertake projects if they did not have the capital for them. They also would not avoid projects that are needed by the community because a CON is required. It's less about de-regulation and more about incentives to change behavior that align with the goals of TCOC model and the triple aim. The goal should be reducing unnecessary utilization and providing the right care in the right setting at the right cost.***

    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?

***There should be exemptions from CON but still requiring quality oversight of some projects such as urgent care.***

<u>The Project Review Process</u>

5. What aspects of the project review process are most in need of reform?

***Adherence to timelines. Timelines are too often not followed. This leads to longer decision times, higher expenses and greater frustration.***
***Subject matter experts are necessary to evaluate some specialty projects.***
***In addition, some aspects of the project review process that tend to slow the process down are:***

- ***Project modifications (perhaps criteria for modifications can be revaluated and/or streamlined)***
- ***Completeness questions (subject matter experts could be a valuable resource) – perhaps narrowing or focusing the scope of the completeness questions.***
- ***HSCRC review of financial feasibility and viability (could be earlier in the process)***
- ***The role of interested parties (they are incentivized to slow down the process)***
- ***Ensure that are at least 2 reviewers well acquainted with or assigned to the project (not relying on one who may have limited knowledge of the subject or who may have schedule conflicts)***
- ***The backlog of applications (give priority to large scope projects, outsourcing smaller scope projects to experts, consultants with specified timeframes for review completion)***

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

***Yes. Interested parties may be restricted on certain projects such as a hospital modernizing with its own capital, in its own service area and not asking for rates. Interested parties should demonstrate adverse impact first, acting as a threshold standard early on in the CON process, not during the project.***

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

***Yes, but they are not adhered to and there should be shorter time frames for smaller scope projects.***

**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?

***The regulations are outdated in some cases, and do not reflect the current environment of the waiver demonstration project, the Affordable Care Act, and the potential new model (ie TCOC, Waiver 2.0). For example, the assessment of need is based on retrospective and historical patterns of utilization under a fee-for-service model versus a forward thinking, predictive analysis under a new payment model (i.e. value-based, utilization avoidance of high cost settings of care).***

***One of the older chapters in the SHP is for psychiatric services (COMAR 10.24.07). With the exception of a minor modification to the occupancy standard in 2013, the chapter has not been updated in over 20 years. Psychiatric services are one of the most critically needed services in our state.***

What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

***Chief strengths – largely open and transparent, fair***

***Chief weaknesses – cumbersome, outdated, "old world of health care" thinking, not in alignment with new reimbursement models, consumer preferences***

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.

***The policies should be critically evaluated in COMAR 10.24.10 – last approved 1/26/09. Currently, there are 19 standards plus service-specific standards. Each should be critically evaluated for relevance, and alignment with the new world order and environment. Specifically, on general standards:***

***Make these part of a "pre-application process" that must be reviewed before a CON is submitted:***

- ***Charges – evaluate how helpful a list of representative charges is to consumers? Is there a better way to inform consumers about charges given the policies and practices of Maryland hospitals? Ask consumers what would be most helpful to make informed decisions. Study other states for best practices.***
- ***Charity care –this should not be a part of the CON process as it is regulated by the HSCRC and embedded in the all payor model.***
- ***Quality - appropriate to be considered as part of CON but coordinate with OHCQ, JCAHO, etc, other agencies.***

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.

***There should be more regular updates, not only when there is a project in the wings. Eliminate or critically evaluate the role of AELR, petitioning the State for changes – only after all avenues have been exhausted. Does the whole commission need to approve need methodology or definitions? Can this be a staff function (can the statute be changed to facilitate technical changes?)***

11. Are these general criteria adequate and appropriate? ***See #9 above***

    Should other criteria be used?

    Should any of these criteria be eliminated or modified in some way?

**<u>Alternatives to CON Regulation for Capital Project –</u>**

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

***No CON should be required for a project when there is no additional revenue being requested for capital or services.***

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

***It is unclear what exact modifications would be needed, but it would be necessary to have an oversight role for the HSCRC to evaluate and approve capital projects.***

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?

***Consider a streamlined, expedited process for low capital-intensive, non-hospital based settings of care such as home health, SNF, hospice, NICU, behavioral health and expansions of beds. CON would be necessary only in the case of a new hospital, new hospital-based regulated services, new market entrants that are UNAFFILIATED with existing systems or hospitals. Create a level playing field.***

**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.

***Incent health system and hospitals to add non-hospital sites of care. Spend less time and give less power to opposing and interested parties. If a health system is demonstrating good QBR performance, moderate margins under GBR, they should be entitled to an expedited process.***

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?

***Isn't that the FTC's job? Of note is the recent Health Affairs article "The Challenging Transformation of Health Care Under Maryland's Global Budgets," December 19, 2017 (Galarraga & Pines). The authors included 3 suggestions, one of which was 'closely monitor hospital solvency and secure access to care through CON programs." Heed this advice. Evaluate the impact of market consolidation and lack of access due to hospital closures.***

**Scope of CON Regulation**

17. 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?)

***No. It should not be eliminated but instead it should be revised waiving the threshold requirement if a hospital is not seeking an increase in its global budget.***

    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.*

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.

***Yes. A pre-application process might be useful.***
***More staff resources are needed as well as subject matter experts (perhaps on a contract basis).***

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

***Establish criteria for eligible projects, adhere to timeframe, (maximum 150 days). See #14.***

<u>The Project Review Process</u>

20. Are there specific steps that can be eliminated?

- ***Evaluate timeframe to docketing and other associated timeframes***
- ***Set limits on when project modifications can be made, site visits can be requested, when completeness questions must be finalized***
- ***Commissioners should be provided a list at each meeting of pending projects – both active and inactive and understand the status of the projects.***

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

***Modifications should be streamlined if certain criteria are met. Can be a staff function.***

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 #14***

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

***Yes, automation would most likely improve the process***

- ***Provide a scoring sheet that is automated that helps an applicant understand if the standards are being met before it is submitted.***
- ***Have available the potential and typical completeness questions in advance***

**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?

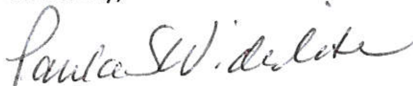
***There needs to be more coordination, not less.***

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

***See #24.***

Thank you for the opportunity to participate in this important endeavor. We look forward to an improved process that helps us meet our mission: improving the health status of the people we serve.

Sincerely,



Paula S. Widerlite
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cc: Brett McCone, Vice President, MHA