Jonathan E. Efron, MD, FACS, FASCRS
Mark M. Ravitch Professor of Surgery
Executive Vice Director, Department of Surgery
Chief, Ravitch Division of Colorectal Surgery

Department of Surgery
600 N. Wolfe Street
Blalock 618
Baltimore, MD 21287
410-955-7323 Office
410-558-6741 Fax
jefron1@jhmi.edu

January 29, 2018

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

Dear Mr. Parker:

Thank you for the opportunity to provide feedback on the Maryland Certificate of Need ("CON") regulatory process as it pertains to Freestanding Ambulatory Surgery Facilities. I offer these comments on behalf of Johns Hopkins Medicine and the following entities: White Marsh Surgery Center (one operating room); Knoll North Endoscopy Center (two non-sterile procedure rooms); Ophthalmology Associates at Greenspring (one operating room); Ophthalmology Associates at Bel Air (two operating rooms); and the Greenspring Station Surgery Center (a five-operating room facility that received CON approval in September 2016 and is under development).

Attached are detailed responses to the survey questions. Johns Hopkins Medicine supports a modification of the Certificate of Need ("CON") requirement that applies to freestanding ambulatory surgery facilities ("FASFs"). One operating room FASFs should, at minimum, be required to receive a CON exemption similar to the requirements enacted in the most recent revision of the Chapter for the addition of a second room to a one-room facility. Currently, there is no review required to open one OR, the significant burden of an exemption request to add a second OR, and even more of a burden to obtain a CON for a two-OR facility or larger. This creates a perverse incentive to develop one OR FASFs, which runs counter to the MHCC's stated preference and also counter to what we believe will result in the best possible care for patients.

In addition, we suggest that quality and safety, potential to reduce overall health care costs, and patient preferences and needs should be meaningful factors in the consideration of exemption and CON requests.

Finally, we recommend that the CON criterion "Availability of more cost-effective alternatives" should be eliminated for FASFs. A proposal to create or expand an FASF is must be financially feasible, and that should continue to be a standard for review. Because financing is not linked to the rate-setting system and instead is at the risk of the developer or owner, there should not be an obligation for applicants to provide a detailed analysis of the alternatives considered and their relative cost-effectiveness. It is a burdensome requirement with no benefit.

Again, thank you for the opportunity to provide input. Please feel free to contact me if you have any questions or would like additional information about our responses.

Sincerely,

Jonathan E. Efron, MD

Jonathan E. Efron, MD, FACS, FASCRS
Mark M. Ravitch Professor of Surgery
Executive Vice Director, Department of Surgery
Chief, Ravitch Division of Colorectal Surgery

Department of Surgery
600 N. Wolfe Street
Blalock 618
Baltimore, MD 21287
410-955-7323 Office
410-558-6741 Fax
jefron1@jhmi.edu

JOHNS HOPKINS
MEDICINE

Johns Hopkins Medicine
Responses to MHCC Survey
January 29, 2018

Please consider your answers in the context of Maryland's 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 FASF 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 FASF CON regulation?

☐ CON regulation of FASFs 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.]

XX CON regulation of FASFs should be reformed.

☐ CON regulation of FASFs should, in general, be maintained in its current form.

Johns Hopkins Medicine recommends maintaining a CON requirement for the establishment or expansion of FASFs in Maryland but advocates for a regulatory framework that no longer incentivizes the creation of one operating room FASFs, that reduces unnecessary administrative burden, and that promotes quality and safety.

ISSUES/PROBLEMS

The Impact of CON Regulation on FASFs Competition and Innovation

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

There is adequate competition among FASFs—indeed, Maryland has more FASFs than any other state. The lack of regulation of one OR FASFs creates a perverse incentive for the creation of these FASFs over larger centers. The biggest impediment to fair competition is the lack of regulation of one OR facilities.

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

The CON requirement provides an appropriate barrier to entry, often resulting in changes to a project that strengthen it and help ensure success. The lack of any barrier to one OR facilities is unfair and creates an uneven competitive environment.

3. How does CON regulation stifle innovation in the delivery of ambulatory surgical services under the current Maryland regulatory scheme?

The plan's focus on a rigid, outdated measure of "minimum utilization" overlooks other potential efficiencies and quality benefits of new facilities or expansions. Minimum utilization has been a threshold requirement that must be met before an FASF can apply to expand, precluding consideration of projects that bring other benefits and are more cost-effective, despite not meeting the utilization threshold.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish an FASF, which is an outpatient surgical center with two or more sterile operating rooms, or relocate an FASF, to expand the operating room capacity of an FASF, or undertake a capital expenditure that exceeds 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 FASF projects that require approval by the Maryland Health Care Commission that should be deregulated?

      No.

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

      Yes. One operating room FASFs should, at minimum, be required to receive a CON exemption similar to the requirements enacted in the most recent revision of the Chapter for the addition of a second room to a one-room facility. Under the current Chapter, there is no review required to open one OR, a significant burden of an exemption request to add a second OR, and even more of a burden to obtain a CON for a 2-OR facility or larger. This creates a perverse incentive to develop one OR FASFs , which runs counter to the MHCC's stated preference and also counter to what we believe will result in the best possible care for patients.

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?

   Completeness questions should be limited to one round and should be limited to information that is essential under the regulations in order to make a ruling on the project.

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

   No—the existing rules are adequate. However, the determination of "qualified for interested party status" should be more rigorous, which is possible under the existing rules.

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? *No.*

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

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

   Greater flexibility could be built into the performance requirements without undermining the purpose of ensuring that projects move forward in a timely manner.

The State Health Plan for Facilities and Services

8. In general, do State Health Plan regulations for FASFs 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?

   Addressed elsewhere in the survey—in general, the SHP regulations provide adequate guidance with consideration for the suggested changes offered here.

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

   The current regulations do not adequately consider safety and quality performance, the role of FASFs in reducing health care costs, or the ways in which FASFs are in some instances able to provide a better patient experience and better meet patient needs.

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.

We appreciate the efforts the MHCC makes during chapter reviews to involve stakeholders and receive broad input. Unfortunately, that input does not always receive full consideration or vetting. There are instances where stakeholders around the table have opposing views. MHCC staff, rather than confronting those issues or guiding the discussion, simply avoids the challenging issues and in this way misses opportunities for real reform and improvement. We would like for there to be more robust conversation throughout the process, not just initially, and to discuss issues with the full commission rather than have staff present a final product that then is subject to a yes or no vote.

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?

Availability of more cost-effective alternatives should be eliminated for FASFs. A proposal to create or expand an FASF is limited by the financial feasibility of the project, and that should continue to be a standard for review. Because financing is not linked to the rate-setting system and instead is at the risk of the developer or owner, there should not be an obligation for applicants to present alternatives and their relative cost-effectiveness. It is a burdensome requirement with no benefit.

CHANGES/SOLUTIONS

Alternatives to CON Regulation

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

Not applicable.

13. 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 FASF licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that FASFs are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization

or poor quality of care?

CON regulation plays an important role distinct from licensure and should be maintained.

The Impact of CON Regulation on FASF Competition and Innovation

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

See our recommendation above regarding regulation of one OR FASFs. The imbalance created under the current system may inhibit innovation.

15. Should Maryland shift its regulatory focus to regulation of the consolidation of ambulatory surgical services to preserve and strengthen competition for these services?

No.

Scope of CON Regulation

16. Should the use of a capital expenditure threshold in FASF CON regulation be eliminated?

Yes. For the reasons cited in response to question 11 above.

17. Should MHCC be given more flexibility in choosing which FASF 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 FASF project to undergo CON review.

While flexibility is important and additional flexibility could reduce the burden on applicants, it runs the risk of creating a system that is arbitrary and unpredictable. We are not in favor of this.

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

A new process is unnecessary and would be burdensome and tax the already limited resources of the regulator. The existing process can be reformed to meet the need for a more efficient and sometimes streamlined process.

The Project Review Process

19. 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 the decision—meaning there are applicable regulations related to that aspect of the project.

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

    Yes. For an FASF project, if the modification is related only to an increase in cost, there should be minimal review and an expedited process. As noted in response to question 11, the developer/owner is at risk for construction costs, and all other requirements were reviewed and ruled upon in the initial review.

21. 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.

    The recent addition of an exemption process to the surgical services chapter was helpful.

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

    Electronic submission of quarterly reports would be helpful but it is not a major obstacle.

Duplication of Responsibilities by MHCC, HSCRC, and the MDH

23. Are there areas of regulatory duplication in FASF regulation that can be streamlined between MHCC and the MDH?

    None known.

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.